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12 UNITED STATES DISTRICT COURT
13 NORTHERN DISTRICT OF CALIFORNIA
14 SAN FRANCISCO DIVISION
15

16 THE CITY AND COUNTY OF SAN
17 FRANCISCO, CALIFORNIA and THE
18 PEOPLE OF THE STATE OF CALIFORNIA,
Acting by and through San Francisco City
Attorney DAVID CHIU,

19 Plaintiffs,

20 v.

21 PURDUE PHARMA L.P., et al.

22 Defendants.
23

Case No. 3:18-cv-07591-CRB

**THE PEOPLE'S PROPOSED
FINDINGS OF FACT AND
CONCLUSIONS OF LAW**

Judge: Honorable Charles R. Breyer

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OVERVIEW

The People of the State of California, acting by and through the San Francisco City Attorney David Chiu, seek recovery from defendant Walgreen Co. (“Walgreens”) to abate a nuisance that has plagued San Francisco, often referred to as the “opioid epidemic.” This epidemic is characterized by extraordinarily high levels of “opioid use disorder” (OUD), the medical term that encompasses what is popularly understood as “addiction,” and the many fatal and non-fatal harms that flow from opioid misuse. Walgreens’ failure to maintain effective controls against the diversion of the dangerous and highly addictive prescription opioids it distributed and dispensed into the community substantially contributed to the harm in San Francisco. As detailed below, this epidemic has affected, and interfered with, public health, public safety, and the comfortable enjoyment of life and property in San Francisco.

To prove a claim for public nuisance, a plaintiff must prove by a preponderance of the evidence that a defendant’s affirmative conduct was a legal cause of a substantial and objectively unreasonable interference with a right common to the public. The facts pertaining to each of these elements—nuisance, affirmative conduct, causation, and substantial and objectively unreasonable interference—are summarized here and discussed in detail below.

Opioids are extraordinarily dangerous drugs with the potential to cause enormous harm, both to individuals and to communities. That harm is evident in San Francisco, where the severity of the opioid epidemic has been described as “worse than catastrophic.” In a typical day, up to 25 percent of all visits to the Emergency Department at Zuckerberg San Francisco General Hospital and Trauma Center (ZSFG ED) are opioid-related. At times, the number of opioid-related visits to the ZSFG ED can be even higher.

San Francisco has been among the top 400 counties in the nation (out of over 3,000) with the highest overdose death rate for each of the last nine years. There have been and remain tremendously high rates of opioid overdose in San Francisco. The prevalence of OUD in San Francisco in 2019 is estimated to be 4.65 percent. In other

1 words, nearly one in twenty San Franciscans suffered from mild to severe opioid addiction
2 in that year. In absolute terms, it is estimated that there were approximately 40,958
3 individuals who had OUD in San Francisco.

4 Although opioids have clear benefits for the relief of severe pain under certain
5 circumstances, such as trauma, surgery, cancer, and palliative care, their potential to cause
6 tolerance, dependence, and addiction, and the allure of using them for non-medical
7 purposes, makes them dangerous as well. For that reason, the drugs have been regulated in
8 the United States and in California for well over 100 years to prevent them from being
9 used other than under appropriate medical supervision. Whatever the benefits of
10 prescription opioids when taken as directed under supervision by a medical professional to
11 treat a *bona fide* medical condition, there is no benefit and no social utility to opioids that
12 have been diverted to non-medical use.

13 Although anyone exposed to opioids is at risk of becoming addicted to them, those
14 who use prescription opioids non-medically are at increased risk. Moreover, use of
15 prescription opioids increases the risk of abuse of illicit opioids such as heroin and
16 fentanyl. Indeed, the natural progression of the disease of opioid addiction is to seek out
17 more potent, plentiful, and cheaper forms over time. It is tragic, but unsurprising, that
18 many people who became addicted to prescription opioids progressed to illicit heroin and
19 fentanyl, which can be significantly more dangerous than prescription opioids themselves.

20 To address the problem of diversion, the manufacture, sale, and dispensing of
21 opioids are tightly controlled under the federal Controlled Substances Act (CSA). As
22 described below, the statute and regulatory framework mandate a “closed system” in
23 which, in order to manufacture, distribute, or dispense opioids, a person or entity must
24 register with the Drug Enforcement Administration (DEA). All registrants under the CSA
25 are required to provide “effective controls against diversion.” Manufacturers and
26 distributors are required to maintain systems to detect “suspicious orders” of opioids, and
27 may not ship such orders until they have determined, through due diligence, that the
28 suspicious order is not likely to be diverted. Dispensers are only permitted to fill

1 “legitimate” prescriptions, which requires them to detect, and clear through due diligence,
2 prescriptions with indicia of diversion, known as “red flags,” before dispensing.

3 Walgreens, the remaining defendant in this case, owns and operates a national
4 chain of retail pharmacies. Walgreens dispenses prescription opioids at its retail stores
5 and, during part of the relevant time period, acted as a wholesale distributor of
6 prescription opioids to its own stores. During the relevant time period, Walgreens enjoyed
7 a dominant market share at 58.7 percent of the retail and chain pharmacy market in San
8 Francisco. Although Walgreens was not the only cause of or contributor to the opioid
9 epidemic, this case focuses on its role in contributing to it.

10 As discussed in detail below, as a registrant under the CSA, Walgreens was and is
11 obliged to maintain effective controls against diversion, but failed to do so in a
12 meaningful way. Indeed, the evidence shows that for substantial portions of the relevant
13 time periods, as a distributor of prescription opioids, Walgreens had virtually no system
14 for detecting and preventing diversion at all. Even when Walgreens purported to adopt
15 such systems, it did not implement them in a meaningful or effective way.

16 As a distributor of prescription opioids, Walgreens was required to operate a
17 system to detect suspicious orders, and to investigate those orders prior to shipping them.
18 But prior to 2012, Walgreens had no meaningful suspicious order monitoring (SOM)
19 system in place. According to Walgreens’ own internal audits, “there was no monitoring
20 process in place to stop a suspicious order to assess if the order is suspicious or not.” In
21 2010, Walgreens’ Divisional Supply Chain Vice President wrote that he did not know
22 who, if anyone, had “been reviewing the [controlled substances order] data collected for
23 the past twenty-five years?” After 2012, Walgreens purportedly put in place a more
24 effective SOM system for its distribution of opioids, but in practice the new system was
25 scarcely more effective than the old one. Two years later, after the DEA shut down one of
26 its three controlled substance distribution centers, Walgreens stopped distributing
27 prescription opioids altogether.
28

1 As a dispenser of prescription opioids, Walgreens was again required to maintain
2 effective controls against diversion and was responsible for dispensing prescription
3 opioids only for legitimate medical purposes. To carry out these responsibilities,
4 Walgreens was required to identify and reasonably investigate prescriptions with objective
5 indicia, or “red flags,” of diversion, and to refrain from filling such prescriptions until the
6 red flags had been cleared.

7 Prior to 2013, Walgreens’ policies for ensuring that only legitimate prescriptions
8 were filled was described by Walgreens itself as “inadequate.” After paying \$80 million to
9 the DEA to settle allegations of CSA violations in 2013, Walgreens instituted new policies
10 with respect to the dispensing of prescription opioids, but as implemented, these new
11 policies likewise failed to provide meaningful or effective controls against diversion.
12 Moreover, Walgreens’ business practices provided incentives for the speedy dispensing of
13 prescription opioids and discouraged the performance and documentation of the due
14 diligence necessary to ensure that opioid prescriptions were dispensed only for legitimate
15 medical purposes.

16 Walgreens had information in its possession that allowed it to identify situations
17 where there was a meaningful risk of diversion, but it routinely disregarded—indeed,
18 *concealed*—this information from its pharmacists in order to keep selling more opioids.
19 Although Walgreens used the information it had for other purposes, it failed to make use
20 of it to prevent diversion, failed to make it available to its pharmacists, and failed to
21 provide its pharmacists with the tools they needed to detect and investigate “red flag”
22 prescriptions. Indeed, Walgreens decided *not* to share data it had identifying doctors
23 whose prescriptions showed indicia of diversion, because it did not want to “cloud the
24 judgment” of its pharmacists with the facts.

25 The evidence shows that Walgreens shipped a significant number of suspicious
26 orders for prescription opioids into San Francisco without due diligence and dispensed a
27 significant number of “red flag” prescriptions at its pharmacies, again without due
28 diligence. The evidence further shows that Walgreens dispensed substantial quantities of

1 opioids pursuant to prescriptions written by doctors who were subsequently disciplined or
 2 prosecuted for writing illegal or illegitimate opioid prescriptions. In many cases,
 3 Walgreens filled these prescriptions long after it knew or should have known about the
 4 physicians' suspicious prescribing patterns, and in some instances, Walgreens continued
 5 filling prescriptions written by these doctors even *after* the doctor's license had been
 6 revoked or suspended. As discussed below, the evidence the People have presented, in its
 7 totality, is sufficient to establish that it is more likely than not that the failure to provide
 8 effective controls against diversion in fact led to significant diversion in San Francisco.

9 Moreover, as described below, the evidence shows that the presence of significant
 10 quantities of diverted prescription opioids distributed and dispensed by Walgreens in San
 11 Francisco substantially contributed to the ongoing opioid epidemic and nuisance. This
 12 effect was in addition to the effect of aggressive marketing by opioid manufacturers and a
 13 corresponding change in prescribing habits that occurred in the 1990s, which led to
 14 significantly increased numbers of opioid prescriptions. Whatever the harms that may
 15 have resulted from this increase in opioid prescribing, that harm was compounded by the
 16 availability of prescription opioids for non-medical use, which occurred through
 17 diversion. Indeed, the overall increase in the number of opioid prescriptions may have
 18 made it harder to detect illegitimate prescriptions, even as it made that detection, and the
 19 controls against diversion required by the CSA, all the more important. Given the quantity
 20 of prescription opioids that Walgreens dispensed in San Francisco, given its market share,
 21 and given the volumes of suspicious orders it distributed and red-flagged prescriptions it
 22 dispensed, it is more likely than not that Walgreens' conduct was a substantial factor in
 23 the creation or maintenance of a nuisance in San Francisco. The Court so finds.

24 **DEFINITIONS**

25 "CSA" means the Controlled Substances Act of 1970, 21 U.S.C. §§ 801–971.

26 "Controlled substance" means a substance scheduled under the CSA. Substances
 27 scheduled under Schedules Two and Three under the CSA may be referred to as "CII" or
 28 "CIII" substances, respectively.

1 “CDC” means the United States Centers for Disease Control and Prevention.

2 “City” means the City and County of San Francisco.

3 “DEA” means the United States Drug Enforcement Administration.

4 “DEA registrant” or “registrant” means a person who is registered with the DEA
5 under the CSA to manufacture, distribute, or dispense controlled substances.

6 “Dispensing” prescription opioids means filling a prescription for opioids.

7 “Distributing” prescription opioids means buying prescription opioids wholesale
8 from manufacturers or other distributors and reselling them wholesale to other distributors
9 or pharmacies, which dispense them.

10 “GFD” means “Good Faith Dispensing,” the name given by Walgreens to its
11 general controlled substances dispensing policies. “TDGFD” means “Target Drug Good
12 Faith Dispensing,” the name given by Walgreens to dispensing policies that applied only
13 to a limited number of “target drugs.”

14 “MME” means “morphine milligram equivalent,” a measure for comparing the
15 relative strengths of different opioids with reference to morphine.

16 “Naloxone,” also called by its brand name “Narcan,” is a drug administered to
17 reverse the effects of opioid overdose.

18 “Opioid” means the class of drugs that bind with opioid receptors in the brain and
19 includes natural (opium-derived) opioids such as morphine and codeine; semi-synthetic
20 (synthesized from natural) opioids such as oxycodone, hydrocodone, oxymorphone, and
21 hydromorphone; and fully synthetic opioids such as fentanyl.

22 “OUD” means “opioid use disorder,” which may be used interchangeably with
23 opioid addiction.

24 “SFDPH” or “DPH” means the San Francisco Department of Public Health.

25 “SFDPW” or “DPW” means the San Francisco Department of Public Works.

26 “SFFD” means the San Francisco Fire Department.

27 “SFRPD” or “RPD” means the San Francisco Recreation and Parks Department.

28 “SOM” means “suspicious order monitoring.”

1 “ZSFG” means Zuckerberg San Francisco General Hospital and Trauma Center.
 2 “ZSFG ED” means the Emergency Department at ZSFG.

3 **PROPOSED FINDINGS OF FACT**

4 The Court finds the following more likely to be true than not, on the basis of the
 5 evidence and the record before it.

6 **I. Parties**

7 **1.** In this lawsuit, Plaintiff the People of the State of California, acting by and
 8 through San Francisco City Attorney David Chiu, seeks relief against Defendant
 9 Walgreen Co. (“Walgreens”) under California’s public nuisance law for the harmful,
 10 hazardous condition constituted by the opioid epidemic alleged to exist in the City and
 11 County of San Francisco.

12 1.1. The People seek relief only for harm arising in San Francisco. Unless
 13 context dictates otherwise, references to the “opioid epidemic” and other prevailing
 14 conditions are limited to San Francisco.

15 **2.** Walgreens owns and operates a national chain of retail pharmacies, including
 16 around 50 pharmacies in San Francisco, which dispense prescription opioids among other
 17 drugs. Until around 2014, Walgreens also distributed controlled substances, including
 18 prescription opioids, to its own pharmacies.

19 **II. F.R.E. 104(a) Determinations**

20 **3.** Among others, the following expert witnesses presented by the People gave
 21 credible, reliable testimony within the scope of their expertise: Carmen Catizone, Dr.
 22 Philip Coffin, Dr. David Herzberg, Dr. Lacey Keller, Dr. Katherine Keyes, Dr. Anna
 23 Lembke, Dr. Craig McCann, and Dr. Elizabeth Park.¹

24 3.1. Carmen Catizone, MS, RPh, DPh, is one of the foremost authorities on the
 25 practice and regulation of pharmacy in the United States. Mr. Catizone holds two

26 _____
 27 ¹ In considering preliminary questions of admissibility, the Court is not limited to the trial
 28 record and “is not bound by evidence rules, except those on privilege.” Fed. R.
 Evid. 104(a). Therefore, in this section, the Court refers to both these experts’ trial
 declarations and Rule 26 reports submitted in connection with the related *Daubert*
 briefing.

1 pharmacy degrees and has practiced as a registered pharmacist for twenty years. From
 2 1988 to 2020, Mr. Catizone was the executive director and CEO of the National
 3 Association of Boards of Pharmacy (NABP), where among other accomplishments he
 4 worked with other stakeholders in the practice of pharmacy, including Walgreens, to
 5 develop a consensus set of “red flag” warning signs for pharmacists to identify and
 6 investigate when dispensing opioid prescriptions. *See generally* Catizone Decl. Ex. A
 7 (curriculum vitae); Catizone Rep. 4–5, 25, 61, 63–65, 76–79, ECF No. 972-5. The Court
 8 finds Mr. Catizone qualified to give reliable testimony about the federal and state-level
 9 regulatory frameworks governing prescription opioids, and about the prevailing standards
 10 of pharmacy practice governing prescription opioid dispensing.

11 3.2. Philip Coffin, M.D., is the director of the SFDPH Center on Substance Use
 12 and Health. He attended the University of San Francisco School of Medicine and his
 13 residency at the Columbia University Medical Center. He is board certified in internal
 14 medicine, infectious disease, and addiction medicine. During his residency, he wrote his
 15 thesis on illicit drug production and markets and spent two months in the Peruvian Andes
 16 studying drug production. In his current position, he has studied substance use, including
 17 OUD, trends and treatment in San Francisco and produces an annual report for the City.
 18 His entire professional career has been dedicated to the study of substance use and abuse.
 19 *See* Coffin Decl. ¶¶ 1–6; Coffin Decl. Ex. 1 (curriculum vitae). The Court finds Dr. Coffin
 20 qualified to give reliable testimony about the present character and history of the opioid
 21 epidemic in San Francisco.

22 3.3. Daniel Herzberg, PhD, is a historian and an associate professor at the
 23 University at Buffalo (State University of New York). His expertise is in the “medical,
 24 commercial, cultural, and regulatory history of psychoactive pharmaceuticals.” Herzberg
 25 Decl. ¶ 1. The Court finds Dr. Herzberg qualified to give reliable testimony about the
 26 medical and regulatory history of prescription opioids in the United States.

27 3.4. Lacey Keller, PhD, is a data analytics consultant who has owned and
 28 operated a data consultancy since 2021, before which she worked as a data analyst for the

1 New York Attorney General and labor unions, among others. *See generally* Keller Decl.
 2 Ex. A (curriculum vitae). The Court finds Dr. Keller qualified to give reliable testimony
 3 about her analyses of physician prescribing data obtained from IQVIA, a data vendor used
 4 among others by Walgreens itself. *See* Keller Decl. ¶¶ 2–3.

5 3.5. Katherine Keyes, PhD, is an epidemiologist and professor at Columbia
 6 University specializing in substance use and substance use disorders, who has been
 7 studying the effects of opioids throughout her career. As an epidemiologist, she examines
 8 public health impacts and sets out to determine their causes. Dr. Keyes has published two
 9 epidemiology textbooks and more than 350 peer-reviewed articles, editorials, and book
 10 chapters, more than 35 of which specifically discuss opioid use and related harms. *See*
 11 *generally* Keyes Decl. ¶ 1–3; Keyes Decl. Ex. 1 (curriculum vitae). The Court finds Dr.
 12 Keyes qualified to give reliable testimony about the population-level impacts of opioid
 13 use nationally and in San Francisco.

14 3.6. Anna Lembke, M.D., has served on the faculty of the Stanford University
 15 School of Medicine since 2003, where she is a Professor, Medical Director of Addiction
 16 Medicine, and Chief of the Addiction Medicine Dual Diagnosis Clinic. As a specialist in
 17 addiction medicine, Dr. Lembke has treated thousands of patients with OUD over the
 18 course of her career. Among other work, Dr. Lembke is the author of *Drug Dealer, MD:*
 19 *How Doctors Were Duped, Patients Got Hooked and Why It's So Hard to Stop* (Johns
 20 Hopkins Univ. Press 2016), and a co-author of the Stanford-Lancet Commission report, an
 21 empirical analysis of the causes of and solutions to the national opioid epidemic. *See*
 22 *generally* Lembke Decl. Ex. A (curriculum vitae); Lembke Rep. 1–7, ECF No. 977-5. The
 23 Court finds Dr. Lembke qualified to give reliable testimony on the proper and improper
 24 use of opioids, opioids' effects, and the nature and causes of addiction, including OUD.

25 3.7. Craig McCann, PhD, is an economist and data computation and analysis
 26 expert. Dr. McCann has decades of academic and professional experience teaching
 27 graduate-level economics and finance courses, serving as an academic fellow for the U.S.
 28 Securities and Exchange Commission, and running a data analysis consultancy. *See*

1 *generally* McCann Decl. Ex. A (curriculum vitae). The Court finds Dr. McCann qualified
 2 to give reliable testimony about the volumes of prescription opioids distributed by,
 3 distributed to, and dispensed by Walgreens that ought to have been identified and
 4 investigated as suspicious orders or red-flagged prescriptions. *See* McCann Rep. 56–75,
 5 ECF No. 960-6.

6 3.8. Elizabeth Park, PharmD, APh, is a California pharmacist and regulatory
 7 consultant holding an advanced practice license and a doctorate in pharmacy. Dr. Park has
 8 performed more than 1,000 regulatory consultations for California pharmacies and
 9 pharmacists, and has served as an independent pharmacist consultant approved by the
 10 California State Board of Pharmacy in more than 50 regulatory proceedings. *See generally*
 11 Park Decl. ¶¶ 1–2; Park Decl. Ex. A (curriculum vitae). The Court finds Dr. Park qualified
 12 to offer reliable testimony on the standard of care for pharmacies and pharmacists
 13 dispensing prescription opioids in California, and on whether Walgreens’ due diligence
 14 files evidence compliance with this standard.

15 **III. Existence of Nuisance**

16 4. Prescription opioids are known to be extraordinarily dangerous drugs with the
 17 potential to cause enormous harm, no matter whether they are used to treat pain or are
 18 used non-medically.

19 4.1. Opioids are among the world’s oldest known drugs. Use of opium from the
 20 poppy plant for medical, recreational, and religious purposes can be traced throughout
 21 history and across continents. The addictive and harmful nature of opioids also has been
 22 known since antiquity. Herzberg Decl. ¶ 2; Lembke Decl. ¶ 6.

23 4.2. In general, opioids have three major neurological effects. First, they bind to
 24 the brain’s pain receptors, temporarily relieving the feeling of pain. Second, they cause the
 25 release of dopamine in the brain, temporarily causing a feeling of pleasure. Third, they
 26 slow the brain stem functions that control heart rate and breathing. Lembke Decl. ¶ 3;
 27 Lembke Trial Tr. 383:23–384:9. Opioids cause death by fatally slowing a person’s heart
 28 rate and breathing. Lembke Decl. ¶ 148; Lembke Trial Tr. 384:5–9.

1 4.3. As a result of opioids’ neurological effects, people who use opioids develop
 2 tolerance and physical dependence. Opioid tolerance decreases or eliminates opioids’
 3 analgesic (pain-relieving) effects and increases the risk of death from opioid overdose;
 4 physical dependence results in painful symptoms of opioid withdrawal if an opioid user
 5 stops using opioids. The process of tapering to end dependence on prescription opioids is
 6 typically protracted and painful. Lembke Decl. ¶¶ 39–44.

7 4.3.1. Neuroadaptation results even when a person has a pain condition and
 8 is taking an opioid to relieve pain. With repeated exposure to opioids, the brain’s natural
 9 pain–pleasure balance begins tilting heavily toward pain, and the person requires
 10 increasing opioid doses or strengths to relieve pain. Lembke Trial Tr. 386:12–23.
 11 Extended or heavy opioid use commonly results in a long-term or permanent neurological
 12 adaption of the brain’s pain–pleasure balance, whereby opioids stop causing pleasure or
 13 relieving pain and instead are now required to maintain homeostasis, that is, required for
 14 the person to feel “normal” and avoid pain. Even relatively brief opioid exposures can
 15 result in “tolerance,” whereby the user requires more of the drug to achieve the same
 16 effects. Opioid tolerant users require more and more, or stronger and stronger, opioids to
 17 maintain “homeostasis” (the balance between pain and pleasure), and relieve the pain of
 18 opioid withdrawal from their prior dose. Lembke Trial Tr. 385:17–386:3; Lembke
 19 Decl. ¶ 3.

20 4.3.2. Opioid-dependent users experience opioid “withdrawal” when they
 21 stop using opioids. Opioid withdrawal symptoms include anxiety, debility, insomnia,
 22 dysphoria, and a distinct, painful physical withdrawal syndrome, including full-body pain
 23 not caused by an underlying pain condition. Lembke Trial Tr. 386:4–23, 387:9–15.

24 4.3.3. Even after using opioids for as little as one month, a person may
 25 experience withdrawal if she abruptly stops using opioids. Zevin Trial Tr. 640:21–641:1;
 26 Coffin Decl. ¶ 55; Coffin Trial Tr. 1903:22–1904:15; Tucker Trial Tr. 2733:10–14.

27 4.3.4. As the opioid dose is increased to overcome tolerance to the pain-
 28 relieving effects of the drug, patients are increasingly exposed to the other dose-dependent

1 risks associated with opioids, including the risk of death. Tolerance to the respiratory
 2 suppressant effects (the ability of opioids to decrease breathing rate and thus blood
 3 oxygenation) develops more slowly than tolerance to the pain-relieving effects of the
 4 drug. As a result, as the dose of opioids goes up to target pain relief, the breathing rate
 5 goes down, increasing the risk of accidental overdose and death. Lembke Decl. ¶ 148.

6 4.3.5. The best scientific evidence, which the Court accepts, demonstrates
 7 that there is an increased risk of death at each level of increased dose, even at very low
 8 doses between 1 and 20 MME per day, and that the risk is particularly elevated at doses
 9 greater than 100 MME per day. Lembke Decl. ¶¶ 21–22.

10 4.3.6. It can take a very long time after a person has stopped using opioids
 11 for the brain to reset itself to normal dopamine levels, such that opioids would no longer
 12 be required to maintain homeostasis. Lembke Trial Tr. 388:5–7.

13 4.3.7. There is a population of millions of patients who have become
 14 physiologically dependent on prescription opioids, sometimes referred to as “legacy”
 15 patients. *See, e.g.*, Lembke Decl. ¶ 39; Coffin Trial Tr. 1908:4–19; 1926:10–11. The
 16 process of tapering off opioids is protracted and difficult, and in some cases patients may
 17 never be able to stop taking opioids even though the drugs are not helping them, because
 18 the drugs have affected the neurocircuitry of the brain to the point where dopamine
 19 equilibrium, or homeostasis, can no longer be restored. Lembke Trial Tr. 392:6–15;
 20 Lembke Decl. ¶ 39.

21 4.4. Prescription opioids carry a high risk of harm even when used as directed by
 22 a doctor. Keyes Decl. ¶ 14, 40.

23 4.5. OUD, or opioid addiction, is a chronic relapsing and remitting disease that
 24 is the result of neurological changes produced by opioid use. OUD is a painful and
 25 destructive disease that is treatable only with great difficulty over months and years.

26 4.5.1. The Diagnostic and Statistical Manual of Mental Disorders (DSM-5)
 27 uses the term “substance use disorder” to denote addiction. Lembke Decl. ¶ 2. The terms
 28 “opioid addiction” and “opioid use disorder” or “OUD” also can be used interchangeably.

1 Lembke Decl. ¶ 2. Some clinicians may apply the term “addiction” for only “severe”
 2 OUD, but no such limitation or definition appears in the DSM-5 itself. Instead, the DSM-
 3 5 defines OUD as a spectrum disorder based on the number of criteria that have been met,
 4 ranging from “mild” (2 to 3 of 11 criteria met), “moderate” (4 to 5 of 11 met), or “severe”
 5 (6 or more of 11 met). *See* P-43472_00003 to 00004. “Addiction” does not have a specific
 6 definition in any version of the DSM; as is true for OUD, there can be mild, moderate, or
 7 severe cases of addiction. The CDC supports this understanding. Keyes Rebuttal Decl.
 8 part I; Keyes Trial Tr. 3549:6–3550:16.

9 4.5.2. The scientific literature has established conclusively that prescription
 10 opioid use is causally related to OUD. Keyes Trial Tr. 2201:7–11. Indeed, it is the greatest
 11 risk factor for developing OUD, and is a greater risk factor than prior substance use
 12 disorder, mental health problems, and other known risk factors. Keyes Trial Tr. at
 13 2205:1–3.

14 4.5.3. OUD is a chronic, relapsing and remitting disease with a behavioral
 15 component, characterized by neuroadaptive brain changes resulting from exposure to
 16 opioids. *See* Lembke Decl. part II.A. OUD is characterized by the continued use of
 17 opioids despite harm to self or others, or despite a desire to quit or cut back. Lembke Decl.
 18 ¶ 2. From a neurological perspective, OUD is a disorder of the brain’s reward circuitry.
 19 Lembke Decl. ¶¶ 3–5.

20 4.5.4. OUD results when the rewiring of a person’s reward circuitry caused
 21 by opioid use drives the person to compulsive, self-destructive consumption that
 22 overcomes the limits of voluntary choice. People with severe OUD commit all available
 23 resources to obtaining more of the substance, even forgoing natural rewards like food,
 24 finding a mate, or raising children. Lembke Decl. ¶ 5.

25 4.5.5. One treatment for OUD is to taper a user to a lower opioid dose while
 26 attempting to avoid withdrawal, but that is not an easy process, particularly for a patient
 27 with a history of substance abuse. Zevin Trial Tr. 664:15–665:8; Coffin Decl. ¶ 55;
 28 Lembke Decl. ¶ 40.

1 4.6. Every human being is vulnerable to the disease of addiction and has the
2 potential to become addicted. This is because addiction affects the same neural pathways
3 that have evolved over millions of years to encourage humans to seek out pleasure and
4 avoid pain. Lembke Decl. ¶ 4.

5 4.6.1. Prescription opioids are as addictive as heroin, because the
6 prescription opioids have the same addictive effects as heroin on the neurocircuitry of the
7 brain. Lembke Decl. ¶ 15.

8 5. Because of the extraordinary dangers they pose, prescription opioids and their
9 use have been subject to conservative regulation by the government and conservative self-
10 regulation by the medical profession, pharmaceutical industry, and associated institutions.

11 5.1. The first opioid epidemic in the United States was contained by the first
12 general effort by governments and healthcare professionals to restrict opioid access and
13 use. Herzberg Decl. ¶¶ 4–5; Herzberg Trial Tr. 1978:20–1979:17.

14 5.1.1. The first opioid epidemic in the United States followed the Civil
15 War. America's consumption of opioids per capita tripled in the wake of the isolation of
16 morphine, the invention of the hypodermic syringe, and unconstrained use of opioids
17 (including opium, laudanum, and morphine) to treat military veterans and housewives.
18 Herzberg Decl. ¶¶ 2–3.

19 5.1.2. In 1897, Bayer chemists synthesized heroin and marketed it as a
20 cough and cold remedy alongside aspirin from 1898 to 1910. Herzberg Decl. ¶ 3.

21 5.1.3. Medical literature in the late 19th Century contains hundreds of
22 detailed case reports of morphine addiction. The same literature showed that the risk of
23 addiction increased in cases where doctors continued to administer, or advised patients to
24 continue to self-administer, hypodermic morphine over long periods of time for protracted
25 illnesses. Herzberg Decl. ¶ 2.

26 5.1.4. By the end of the 19th Century, the first opioid epidemic had
27 persuaded leading physicians that opioids were dangerous and should be used as sparingly
28 as possible. Herzberg Decl. ¶ 4.

1 5.1.5. San Francisco passed the first municipal ordinance regulating opioids
 2 in 1875, requiring that opium be safely labeled and sold by licensed pharmacists. Reforms
 3 culminated in the federal Harrison Anti-Narcotic Act of 1914, which required that opioids
 4 be sold only by prescription for legitimate medical purposes. Herzberg Decl. ¶ 5;
 5 Herzberg Trial Tr. 1975:18–1976:4, 1977:22–1978:2.

6 5.2. For most of the 20th Century, governments and healthcare professionals
 7 continued to restrict opioid access and use in light of opioids’ known dangers. Herzberg
 8 Trial Tr. 1975:20–1976:4.

9 5.2.1. The Harrison Anti-Narcotic Act of 1914 was amended in 1942 to
 10 effectively make heroin illegal. Herzberg Decl. ¶ 5.

11 5.2.2. The contemporary regime of governmental opioid regulation was
 12 inaugurated by the passage of the CSA in 1970. Herzberg Decl. ¶ 10. Under this regime, a
 13 “controlled substance” is one that is scheduled under the CSA. Rannazzisi Dep. 405:12–
 14 14; Catizone Decl. ¶ 6. The CSA contains five schedules. Schedule I substances are drugs
 15 without any medical use and the highest potential for abuse, such as heroin. Schedule I
 16 substances may not be prescribed or lawfully used for any purpose. Schedule II substances
 17 are drugs that have a high potential for abuse and some medical uses. These drugs may be
 18 prescribed by licensed practitioners, but access to them is tightly controlled because of the
 19 risks associated with non-medical use of them. Most commonly prescribed opioids—such
 20 as oxycodone, hydrocodone, and fentanyl—are Schedule II drugs. Rannazzisi Dep.
 21 405:12–14, 405:21–406:1, 407:11–15, 407:17–408:10; Catizone Decl. ¶¶ 6–7.

22 5.2.2.1. The CSA and its regulations limit the persons who are
 23 authorized to lawfully handle controlled substances to those who are registered with the
 24 DEA, or “registrants.” Controlled substance manufacturers, distributors, and dispensers
 25 (such as pharmacies, though not individual pharmacists) are all registrants under the CSA.
 26 Rannazzisi Dep. 410:21–413:1.

27 5.2.2.2. CSA registration is intended to create a “closed system” of
 28 distribution for opioids and other controlled substances. The closed system means that, at

every step taken by every opioid pill (or patch, lozenge, or other delivery method) down the opioid supply chain, a specific registrant is legally accountable for that pill (or patch, etc.). This system of accountability is intended to secure the opioid supply chain against diversion. Rannazzisi Dep. 436:10–437:25; P-03669_00001; Catizone Decl. ¶ 9.

5.2.2.3. In general, the closed system of opioid distribution has two steps: from manufacturers to distributors, and from distributors to pharmacies. Manufacturers take raw materials and produce a finished opioid product. Manufacturers then ship finished opioid products to distributors, who distribute opioids to pharmacies and other dispensers like hospitals. Rannazzisi Dep. 439:23–440:22; Catizone Decl. ¶ 9.

5.2.2.4. In the context of controlled substances, “diversion” means that the controlled substances are “taken from ... the legitimate stream of commerce and moved into the illicit marketplace,” outside the closed system. Rannazzisi Dep. 382:2–5. The CSA requires the DEA to consider the “maintenance of effective controls against diversion ... *into other than legitimate medical, scientific, research, or industrial channels.*” 21 U.S.C. § 823 (emphasis added). In the context of pharmacy dispensing, it is the use of opioids for other than legitimate medical purposes that constitutes diversion. Catizone Decl. ¶ 10.

5.2.2.5. Diversion is *per se* harmful to the public. Even small amounts of diverted opioids can cause serious harm. Rannazzisi Dep. 392:10–18; P-03669_00002. Put simply, diversion causes death. Rannazzisi Dep. 427:2.

5.2.2.6. Because of the serious danger to public health and safety posed by even small amounts of diversion, every registrant under the CSA is required to maintain “effective controls” against diversion. Rannazzisi Dep. 410:13–15, 411:10–15, 417:20–22, 444:15–16; P-03669_00002. Both the letter and the spirit of the CSA and its regulations impose a shared responsibility on all registrants to maintain the closed system of distribution. Rannazzisi Dep. 449:12–450:18; P-03669_00002. A registrant’s failure to observe this obligation leads to diversion, which in turn leads to serious public health harms. Rannazzisi Dep. 426:6–427:2.

5.2.2.7. The requirement of registrants to maintain effective controls against diversion is multifaceted, and includes among others recordkeeping, auditing, and inventorying requirements. Rannazzisi Dep. 443:7–444:8; *see* Coman Trial Tr. 765 These requirements are onerous, Rannazzisi Dep. 444:5–8, precisely because of the danger opioids pose to public health and safety, especially when used non-medically.

5.2.3. As a result of the conservative governmental regulation and professional self-regulation, no crises linked to prescription opioids occurred in the United States through the 1980s. The opioid crises that were seen during this time generally were smaller in scale and involved illicit heroin rather than medically prescribed drugs. These smaller crises were addressed through a combination of strategies, most successfully with expanded treatment options, which (beginning in 1965) included methadone maintenance. Herzberg Decl. ¶ 5.

6. In a pattern familiar to the pharmaceutical and healthcare industries, repeated efforts to liberalize governmental and self-regulation of prescription opioids have led to repeated public health crises. Herzberg Decl. ¶¶ 6–10.

7. There is an opioid epidemic—an epidemic of opioid misuse, abuse, addiction, and overdose—in San Francisco.

7.1. “Epidemic,” defined as an outbreak of disease that spreads quickly and affects many individuals at the same time, is the appropriate term to describe the increase in opioid-related morbidity and mortality beginning in the 1990s and continuing to the present day. Lembke Decl. part III.Q.

7.2. The epidemic of opioid-related harm in the United States began with a rapid increase in prescription opioid overdose death. The opioid supply increased dramatically in the United States beginning in the mid 1990s, and a direct consequence of the increased supply of opioids was an increase in the incidence and prevalence of OUD among both medical patients and non-patients, and an increase in prescription opioid-related deaths in the late 1990s and early 2000s. Keyes Decl. ¶ 22

1 7.3. The severity of the opioid epidemic in San Francisco is worse than
2 catastrophic. Zevin Trial Tr. 632:4–8; *see also* Colwell Decl. ¶¶ 3–12.

3 7.4. Walgreens does not dispute the existence of an “opioid crisis” in San
4 Francisco. *See* Trial Tr. 3969:18–21.

5 8. The opioid epidemic interferes with the public health in San Francisco. The
6 interference is substantial, significant, and has long-lasting effects.

7 8.1. In a typical day, up to 25 percent of all visits to the ED at ZSFG are opioid-
8 related. At times, the number of opioid-related visits to the ZSFG ED can be even higher.
9 Colwell Decl. ¶ 9.

10 8.2. The opioid epidemic is hazardous to the health of San Franciscans from all
11 walks of life. Patients who arrive at the ZSFG ED after a fentanyl overdose or with
12 opioid-related health complications come from a variety of backgrounds. Colwell Decl.
13 ¶¶ 11–12. Among the people seen by the Chief of the ED at ZSFG, Dr. Christopher
14 Colwell, for medical issues related to opioid use and overdose were a physician, two
15 nurses, lawyers, a professional athlete, a drug dealer, a 14-year-old, and a 7-year-old who
16 got into a stash of pills in her mother’s purse. Colwell Decl. ¶ 12.

17 8.3. There is a significant and ongoing public health burden of OUD and opioid
18 overdose in San Francisco. San Francisco has been among the top 400 counties in the
19 nation (out of over 3,000) with the highest overdose death rate for the last nine out of nine
20 years. There have been and remain tremendously high rates of opioid overdose in San
21 Francisco. Keyes Decl. ¶ 23; *see* Keyes Decl. ¶¶ 105–22.

22 8.4. The prevalence of OUD in San Francisco in 2019 is estimated to be 4.65
23 percent. In other words, nearly one in twenty San Franciscans suffered from mild to
24 severe opioid addiction in that year. In absolute terms, it is estimated that there were
25 approximately 40,958 individuals who had OUD in San Francisco in 2019, who may be in
26 need of treatment services. Keyes Decl. ¶¶ 25, 48, 128–29; Keyes Trial Tr. 2224:21–
27 2225:6. This may be a conservative estimate in San Francisco due to the local programs
28 providing distribution and access to naloxone to reverse overdose. Keyes Decl. ¶ 129.

1 8.5. Over the course of the past three decades, within the universe of patients
 2 experiencing homelessness in San Francisco, there has been a steady increase in patients
 3 suffering from OUD. Zevin Decl. ¶ 5. The acceleration within the past ten years has been
 4 especially substantial. Zevin Decl. ¶ 5. Of the substance use disorders in patients treated
 5 by Dr. Barry Zevin, an addiction medicine doctor who is currently the medical director of
 6 the Street Medicine, Shelter Health, and Urgent Care program operated by the San
 7 Francisco Health Network, Zevin Decl. Ex. A, OUD is the most prevalent. Zevin Decl.
 8 ¶ 4.

9 8.6. In addition to an increase in the sheer number of patients with OUD, there
 10 also has been a change in the demographic of this patient population. Zevin Decl. ¶ 5.
 11 Thirty years ago, most such patients had begun using opioids recreationally as young
 12 adults. Zevin Decl. ¶ 5. Now, many of the OUD patients seen by Dr. Zevin started using
 13 prescription opioids later in life. Zevin Decl. ¶ 5.

14 8.7. In San Francisco, the number of fatal opioid overdoses in 2020, the most
 15 recent year of available data, was 584. Coffin Decl. ¶ 39.

16 8.8. Drug overdoses in San Francisco are common and have been the leading
 17 cause of death since 2016 among those experiencing homelessness. Zevin Decl. ¶ 6.

18 8.9. Opioid-related overdoses kill more of Dr. Zevin's patients now than
 19 HIV/AIDS did in the 1990s (when there were no reliable treatments for AIDS). Zevin
 20 Decl. ¶ 6. Dozens of Dr. Zevin's patients and hundreds of SFDPH Street Medicine
 21 patients die as a result of the opioid epidemic each year. Zevin Trial Tr. 632:19–24.

22 8.10. The number of non-fatal overdoses is conservatively estimated to be
 23 approximately seven times higher than the number of fatal overdoses. Keyes Decl. ¶ 134.
 24 By this estimate, in San Francisco at least 1,939 people experienced at least one non-fatal
 25 overdose in 2019 (5 to 6 people per day). Keyes Decl. ¶ 135.

26 8.11. SFDPW personnel encounter as many as seven overdose cases per week
 27 on the streets of San Francisco. Short Trial Tr. 1966:1–23.

28

1 8.12. As of June 2016, the ED at ZSFG was responding to approximately four to
 2 six incidents of opioid-related overdoses per day—including overdoses treated in the ED
 3 and calls the ED received from the field about people who overdosed on opioids but
 4 refused transport after treatment or were declared dead at the scene following an overdose.
 5 Colwell Decl. ¶ 4.

6 8.13. Today, the ZSFG ED sees approximately 10 to 20 opioid-related overdose
 7 incidents every day—a substantial increase over the last six years. Approximately 50
 8 percent of these opioid-related overdoses involve fentanyl; 25 percent involve prescription
 9 opioid pills; and the remaining 25 percent involve other substances, generally heroin or
 10 another opioid. Colwell Decl. ¶ 5.

11 8.14. The number of opioid overdose calls to the SFFD Emergency Medical
 12 Services (EMS) has increased “dramatically,” particularly calls for overdoses on the
 13 street. Tong Decl. ¶ 3; *see also* Tong Trial Tr. 1351:17–21, 1352:2–6.

14 8.15. Today, opioid overdose is so common that naloxone is administered by
 15 EMS as a matter of course to people found unresponsive on the street when other
 16 interventions fail. Tong Decl. ¶ 7. People found unresponsive on the street with any
 17 indicia of opioid use nearby, such as pill bottles, are also administered naloxone. Tong
 18 Decl. ¶ 7; Tong Trial Tr. 1355:17–20 (“Are there pills? Are there needles?”). Even
 19 ordinary people have started carrying naloxone in case they are able to help someone
 20 overdosing on the street. Tong Trial Tr. 1361:17–20, 1362:2–7.

21 8.16. Between July 2018 and March 2022, SFFD administered more than 7,600
 22 doses of naloxone on at least 7,415 separate occasions. Each of these doses reflects an
 23 actual or suspected opioid overdose. Tong Decl. ¶ 6; Tong Trial Tr. 1353:2–7, 1353:22–
 24 25. That the number of doses is higher than the number of patients reflects the fact that the
 25 fentanyl overdoses of recent years may require two or more doses to revive a patient—if
 26 they are able to revive the patient at all. Tong Decl. ¶ 8; Tong Trial Tr. 1356:10–23.
 27 Today, EMS administers naloxone about six to eight times a day, or 180 times a month.
 28 Tong Trial Tr. 1354:1–4, 1354:9–12. But these figures do not capture the full number of

1 opioid overdoses treated in San Francisco. Other City agencies (including the police
2 department), nonprofit organizations, and two private ambulance companies also
3 administer naloxone to reverse opioid overdoses. Tong Decl. ¶ 6; Tong Trial Tr. 1353:13–
4 21.

5 8.17. The number of patients presenting at the ZSFG ED with other opioid-
6 related health conditions besides overdose has increased steadily over the last six years,
7 since 2016. Colwell Decl. ¶ 7.

8 8.17.1. Some of these opioid-related health conditions manifest in patients
9 who are in the throes of OUD and who neglect their basic needs because the craving for
10 opioids has become an all-consuming compulsion. The ZSFG ED sees an increasing
11 number of these patients who are badly malnourished or dehydrated. The ZSFG ED also
12 sees increasingly more patients suffering from OUD with hypothermia from exposure or
13 with conditions like diabetic ketoacidosis who are unable to care for their medical needs
14 because of the all-consuming nature of their opioid addiction. Colwell Decl. ¶ 8.

15 8.17.2. The ZSFG ED also sees more and more patients who have
16 developed sepsis, localized infections or abscesses from unsterile injection practices like
17 “skin popping,” an under-the-skin method used to inject drugs when veins become
18 difficult to access. Colwell Decl. ¶ 8.

19 8.18. Overall, the number of opioid-related ED visits more than tripled from
20 2015 (886 ED visits) to 2020 (2,998 ED visits). Coffin Decl. ¶ 40.

21 8.19. Approximately 17,000 children in San Francisco have been exposed to
22 parental opioid abuse. These children can be expected to experience a heavy burden of
23 psychiatric and learning disorders throughout pre-school and school-age. Rates of
24 psychiatric and learning disorders are approximately 2 to 3 times higher among children
25 who experience parental drug use and parental separation or death. ADHD,
26 depression/anxiety, and PTSD are among the leading disorders in children associated with
27 parental drug use. Keyes Decl. 54 tbl.3.

1 8.20. Neonatal abstinence syndrome (NAS) occurs when infants are born
 2 exposed to opioids *in utero* and experience withdrawal symptoms after birth. NAS is
 3 associated with significant medical morbidity, from low birthweight and general
 4 discomfort and pain for the infant to serious health issues such as respiratory disorders and
 5 seizures. Cases of NAS can have long-lasting effects on infants, as the clinical literature
 6 has documented increased incidence of developmental delays and child behavior problems
 7 into childhood. NAS is challenging clinically to treat and remains associated with adverse
 8 long-term outcomes. In California, there was a 300 percent increase in the incidence of
 9 NAS from 1999 through 2013, from 1.5 per 1,000 hospital births to 6 per 1,000. NAS
 10 continues to be a heavy burden in California. Keyes Decl. ¶ 140.

11 8.21. “Suicide by opioid,” that is, intentional rather than accidental fatal
 12 overdose, has impacted mortality in California. The rate of suicide using opioids has more
 13 than doubled in the United States from 1999 to 2019, from 0.22 per 100,000 to 0.51 per
 14 100,000. California has seen significant increases in suicide deaths involving opioids in
 15 that same time period. Keyes Decl. ¶ 141.

16 8.22. In California, opioid-related inpatient hospital stays more than tripled in
 17 per capita terms in less than 15 years, from 114.4 per 100,000 population in 2005 to
 18 355.17 per 100,000 population in 2017. Keyes Decl. ¶ 142.

19 8.23. San Francisco has experienced a heavy public health burden as result of
 20 the opioid epidemic. There remains a substantial burden of unmet treatment need in San
 21 Francisco, and a high prevalence of OUD. The collateral damage of the opioid epidemic is
 22 experienced throughout San Francisco, including by children and families of those
 23 affected by overdose, who have higher rates of psychiatric disorders and other detrimental
 24 health outcomes. Keyes Decl. ¶ 143.

25 9. The opioid epidemic interferes with the public convenience in San Francisco,
 26 including with public rights of way, public rights of access, and the effectiveness of public
 27 agencies and other institutions serving the public. The interference is substantial,
 28 significant, and has long-lasting effects.

1 9.1. The opioid epidemic has had a profound impact on the San Francisco
2 Department of Public Works, its approximately 1,600 employees, and the work that they
3 do for the benefit of all people in San Francisco. Short Trial Tr. 1962:2–5.

4 9.1.1. More than 300 SFDPW employees are part of the Street
5 Environmental Services Bureau who work to keep the city’s streets and sidewalks clean
6 and accessible twenty-four hours a day, seven days a week. Short Trial Tr. 1962:2–7.

7 9.1.2. These dedicated public servants are mostly general laborers who
8 often are not trained or prepared for the reality of the crises they encounter throughout the
9 city. Short Trial Tr. 1968:19–22. The human feces and vomit—much of which is likely
10 associated with drug use—DPW staff encounter on the streets are some of the least
11 distressing things they come across. Short Trial Tr. 1962:22–24. Some DPW employees
12 have found the bodies of those who have died from an overdose or otherwise on the
13 streets. Short Trial Tr. 1968:16–18.

14 9.1.3. More than 95,000 needles have been collected in each of the 2017,
15 2018, 2020, and 2021 fiscal years. Short Trial Tr. 1962:13–16. Thus far, in the 2022 fiscal
16 year, from July 2021 until February 2022, more than 78,000 needles have been
17 collected—exclusive of needles collected at kiosks, Short Trial Tr. 1962:17–21, and by
18 zone crews who help monitor and clean various portions of the city. Short Trial Tr.
19 1969:11–1970:1.

20 9.1.4. Although DPW employees are trained to properly dispose of needles
21 and other types of sharps, their fears have been realized when they have been pricked by
22 dirty, used needles. Short Trial Tr. 1967:22–1968:1. DPW Interim Director Carla Short
23 has personally counseled four employees in the aftermath of such an experience. Short
24 Trial Tr. 1968:2–6.

25 9.1.5. DPW has had to install (and upgrade, when the first installation
26 failed) needle grinders in public toilets to prevent clogging of pipes by discarded needles.
27 Short Trial Tr. 1965:13–25.
28

1 9.2. The opioid epidemic regularly prevents the public’s use and enjoyment of
 2 public spaces, including streets, sidewalks, and public gathering places. Short Trial
 3 Tr. 1970:2–1971:17. Any public space in San Francisco may attract opioid use and
 4 quickly be rendered unusable to the public.

5 9.2.1. In places like Jose Coronado Park sidewalks have been narrowed to
 6 keep them accessible to the public and prevent locations from being used to camp or
 7 otherwise be blocked. Short Trial Tr. 1971:8–17.

8 9.2.2. Near Jose Coronado Park, DPW developed a plaza called “McCoppin
 9 Hub.” Short Trial Tr. 1970:2–10. Meant to be a space for food trucks to pull up and for
 10 the community to gather, the plaza became a common place for the public use of opioids.
 11 Short Trial Tr. 1970:2–15. Unable to keep up with the resulting large amount of debris
 12 including sometimes hundreds of needles, DPW installed a large metal fence with locking
 13 door. Short Trial Tr. 1970:11–25. The Plaza is now locked and off limits except for
 14 special events. Short Trial Tr. 1970:18–25.

15 9.2.3. Encountering opioid overdose victims on the streets of San Francisco
 16 is “the new normal.” Tong Decl. ¶ 9. So common are opioid overdoses on the streets of
 17 San Francisco that SFFD EMS has stopped waiting to be called in, and has started
 18 proactively patrolling the worst-affected neighborhoods to intervene wherever “sedated or
 19 unresponsive” people can be found. Tong Decl. ¶ 19.

20 9.2.4. The opioid epidemic regularly interferes with the public’s access to
 21 and use of San Francisco’s public libraries.

22 9.2.4.1. The San Francisco Public Library is a nationally recognized,
 23 award-winning public library system. Lambert Decl. ¶¶ 2–3; P-29368; P-29370. It has
 24 been “devastat[ed]” by the opioid epidemic in San Francisco. Lambert Trial Tr. 948:14–
 25 18.

26 9.2.4.2. People “routinely” use opioids in the main library branch, or
 27 “Main Library.” Lambert Decl. ¶ 4; *see also* Lambert Trial Tr. 945:2–12. Discarded
 28 needles are found lying around the children’s section, in restrooms, hidden in the stacks,

1 and even slipped between the pages of books. Lambert Decl. ¶ 4; Lambert Trial
2 Tr. 945:13–946:2.

3 9.2.4.3. Librarians must take care that they are not stuck by discarded
4 needles as they restock the Library’s shelves. Two library staff have already been injured
5 by discarded needles. Lambert Decl. ¶ 4; Lambert Trial Tr. 945:21–946:6. Ordinary
6 library patrons face the same risks. Lambert Decl. ¶ 5; *see* Lambert Trial Tr. 948:11–15.

7 9.2.4.4. The Library’s “incident tracker,” which records violations of
8 the Library’s Patron Code of Conduct, contains reports from across the Library’s 27
9 locations of opioid use, opioid overdose, unconsciousness due to opioid use, and acting
10 under the influence of opioids. Lambert Decl. ¶ 8; Lambert Trial Tr. 946:9–947:13.
11 Opioid use at the Library’s locations “runs the gamut” from fentanyl to pills. Lambert
12 Trial Tr. 947:10–13.

13 9.2.4.5. The current City Librarian, Michael Lambert, began his career
14 reading aloud to children. Lambert Trial Tr. 943:24–25. He now patrols the floors of the
15 Main Library looking for and trying to help overdose victims. Lambert Trial Tr. 951:19–
16 952:5.

17 9.2.4.6. Sharps containers have been installed in the Main Library’s
18 children’s section and restrooms. Lambert Decl. ¶¶ 4, 10. So many needles are flushed
19 down toilets that the Main Library has installed two different sets of grinding equipment
20 in the plumbing, which grinds up the discarded needles and keeps the pipes clear. Lambert
21 Trial Test. 948:24–949:4.

22 9.2.4.7. Before the grinding equipment was installed, the Main Branch
23 was regularly required to shut down the library and have City plumbers clear the needles
24 from the pipes. These shutdowns caused system-wide loss of access to resources found
25 only at the Main Branch, such as the San Francisco History Center (the City’s official
26 archive) and the Hormel Center for LGBTQIA. Lambert Decl. ¶ 11; Lambert Decl.
27 Exs. C–D; Lambert Trial Tr. 949:5–24.
28

1 9.2.5. The opioid epidemic regularly prevents the public from using public
2 parks and similar public spaces.

3 9.2.5.1. SFRPD serves more than 220 parks, playgrounds, recreations
4 centers, various sports fields, and buildings in San Francisco. Follin Decl. ¶ 2. It has
5 approximately 40 park rangers and five sergeants who serve as Head Park Rangers. Follin
6 Decl. ¶ 2.

7 9.2.5.2. In the public spaces for which SFRPD is responsible, Head
8 Park Ranger Maja Follin has seen people doing drugs “on view,” in RPD parlance, and
9 has found prescription opioids (“the lollipops which look like a longer stick kind of swab-
10 type thing” and pill bottles) and opioid paraphernalia, including syringes. Follin Trial
11 Tr. 2066:19–2067:11.

12 9.2.5.3. RPD personnel regularly interact with San Francisco’s
13 homeless population. Among this population, RPD personnel often see signs of opioid
14 abuse in the parks, including used needles, and encounter individuals who appear
15 impaired or are actively overdosing. Follin Decl. ¶¶ 4, 9; Follin Trial Tr. 2065:22–
16 2066:21.

17 9.2.5.4. All RPD park rangers are trained to use naloxone in the event
18 they encounter someone who is overdosing on opioids and carry it. Follin Decl. ¶ 7. Since
19 2019 rangers have had to give or facilitate the administration of naloxone approximately a
20 dozen times; one ranger has had to do so three times. Follin Decl. ¶ 8.

21 9.2.5.5. In 2019 alone, RPD environmental services staff collected
22 more than 10,000 needles in the parks. Follin Decl. ¶ 9. Rangers regularly fill sharps
23 containers in patrol cars. For RPD personnel, finding needles in the parks is as common as
24 having to change toilet paper in the restrooms. Follin Decl. ¶ 11.

25 9.2.5.6. The presence of needles and feces—likely related to opioid
26 abuse—interferes with the public’s ability to access the parks. Needles are found on
27 playgrounds, posing a danger to children and others. There are even challenges to keeping
28 newly renovated facilities open because of opioid abuse. RPD staff struggle to keep

1 restrooms open and in safe condition because of the needles found in them every few
2 hours. Follin Decl. ¶ 13.

3 9.2.5.7. Stairwells in Civic Center Plaza have had to be closed once or
4 twice a week between 2019 and 2021 because of the massive quantities of needles found
5 there. Follin Decl. ¶ 14.

6 9.3. The opioid epidemic has taken a severe toll on medical personnel working
7 in San Francisco. At the ZSFG ED, the need to respond to a large and increasing number
8 of overdoses, overdose deaths, and patients with opioid-related health conditions has
9 resulted in burnout and a sense of hopelessness among some doctors, nurses, and other ED
10 staff. Colwell Decl. ¶ 9.

11 9.4. The City and its agencies have expended substantial resources on
12 extraordinary, proactive, and innovative measures which have helped mitigate some of the
13 worst effects of the opioid epidemic in San Francisco, but the problem is so severe that
14 these measures have not been enough to abate it.

15 9.4.1. The measures include intensive interventions involving naloxone,
16 buprenorphine, methadone, and outreach programs. Coffin Trial Tr. 1905:20–22; Coffin.
17 Decl. ¶¶ 14–15, 28–29.

18 9.4.2. The measures include inward and outward facing programs created
19 by SFDPPW to assist both employees and members of the public afflicted by opioid use
20 disorder and its associated harms. In the wake of traumatic experiences, SFDPPW Director
21 Short encourages employees to seek help from trained counselors in the employee
22 assistance program and other mental health resources offered by the Department’s award-
23 winning wellness program. Short Trial Tr. 1969:1–10.

24 9.4.3. In response to the needles and human waste related to and caused by
25 the opioid epidemic, SFDPPW created a “Pit Stop” program in 2014 that established
26 public, monitored restrooms throughout the city. Short Trial Tr. 1962:25–1963:4. These
27 safe spots, located throughout the city are meant to provide those who might not otherwise
28 have access, a safe, clean, and dignified way to use the restroom and, in turn, help rid the

1 streets and sidewalks of human waste. Short Trial Tr. 1963:5–9. The restrooms contain
 2 syringe kiosks and are checked between each use by four non-profit Public Works partner
 3 organizations. Short Trial Tr. 1965:9–12. Throughout the COVID-19 pandemic Public
 4 Works added additional, similar resources in other locations throughout the city. Short
 5 Trial Tr. 1965:5–8.

6 9.4.4. Dr. Christopher Colwell and the ZSFG ED have taken concrete steps
 7 to try to identify and address the risks and devastating impacts of opioid addiction.
 8 Colwell Decl. ¶ 13.

9 9.4.4.1. For example, the ED suggested limitations in prescribing
 10 opioids to only 15 pills at once and providing naloxone with every opioid prescription.
 11 Colwell Decl. ¶ 13.

12 9.4.4.2. The ED also has developed and implemented an opioid-
 13 withdrawal program using buprenorphine. Colwell Decl. ¶ 13.

14 9.4.4.3. Nevertheless, additional measures and the resources to
 15 implement them will be needed to reduce the alarming number of deaths and other
 16 medical conditions caused by opioids in San Francisco. Colwell Decl. ¶ 13.

17 9.4.5. Like ZSFG ED, SFFD EMS has adopted proactive and innovative
 18 measures to control the opioid epidemic, Tong Decl. ¶ 4, but they have not been enough.

19 9.4.5.1. “EMS-6,” a program restarted in 2016, refers patients to
 20 detoxification and treatment facilities to help “break the cycle” of overdose and
 21 hospitalization. Tong Decl. ¶¶ 11–12; Tong Trial Tr. 1358:12–1359:6.

22 9.4.5.2. “Project FRIEND” distributes naloxone to community
 23 members. Tong Decl. ¶¶ 13–14; Tong Trial Tr. 1359:9–20.

24 9.4.5.3. The “Street Overdose Response Team” or “SORT” intervenes
 25 with patients who have recently overdosed and tries to help them access health care and
 26 other services. Tong Decl. ¶ 15; Tong Trial Tr. 1362:14–1363:5. Since starting in August
 27 2021, SORT has intervened in over 1,200 cases, and in over 600 opioids cases, at a rate of
 28 100 interventions per month. Tong Decl. ¶¶ 16–17; Tong Trial Tr. 1363:8–22. SORT has

succeeded in getting buprenorphine treatment (similar to methadone treatment) to about 49 patients. Tong Decl. ¶ 16; Tong Trial Tr. 1363:23–1364:1.

9.4.5.4. The “Street Wellness Response Team” or “SWRT” practices “preventative EMS,” Tong Trial Tr. 1364:24, by proactively canvassing the worst-hit neighborhoods like the Tenderloin and SOMA to intervene wherever people who might be overdosing can be found. Tong Decl. ¶ 18–19; Tong Trial Tr. 1364:14–1365:4. This prophylactic program may be the first of its kind in the nation. Tong Trial Tr. 1365:5–8.

9.4.6. Like other City agencies, the Library has taken proactive and innovative measures to mitigate the effects of the opioid epidemic, but they have not stopped the number of reports submitted to the Library’s “incident tracker” from increasing. Lambert Decl. ¶¶ 8–24.

9.4.6.1. The Library is the first in the nation to employ a full-time social worker, who manages the Library’s Social Services Program. Lambert Decl. ¶ 9. The Program connects homeless or ill Library patrons with needed services, and also attends to the mental health of Library staff, who have witnessed substance abuse and overdoses on Library premises. Lambert Decl. ¶ 9; Lambert Trial Tr. 947:16–948:10; *see* Lambert Trial Tr. 950:2–7 (fatal overdose in 2017 in Main Library); Lambert Decl. ¶ 12 (“It was awful to witness this person’s blue body being removed from the library.”).

9.4.6.2. The Library has offered voluntary training in naloxone administration to its staff. Lambert Decl. ¶¶ 12–13; Lambert Trial Tr. 950:10–21. More than 100 staff have received the training, including City Librarian Michael Lambert, and they have reversed 42 opioid overdoses on Library premises. Lambert Decl. ¶¶ 13–14; Lambert Trial Tr. 950:14–21.

9.4.6.3. The Library has trained its staff to perform CPR, de-escalation, and crisis intervention. Lambert Decl. ¶ 15; Lambert Trial Tr. 951:7–16.

9.4.6.4. The Library has contracted with a nonprofit organization called Urban Alchemy to time patrons’ restroom use. If patrons spend “more than 8 to 10 minutes” in a restroom, Urban Alchemy restroom attendants will begin checking for

unresponsiveness and possible overdose. Lambert Decl. ¶ 21; Lambert Trial Tr. 952:25–953:12.

10. The opioid epidemic constitutes a public nuisance in San Francisco that undisputedly is injurious to health, interferes with the comfortable enjoyment of life, and interferes with rights common to the public, including the rights to public health and safety, as well as public access to parks, libraries, and other recreational spaces. *See* paras. 8–9, *supra*.

11. The opioid nuisance in San Francisco affects entire neighborhoods and communities, and a considerable number of San Franciscans. *See* paras. 8–9, *supra*.

12. The opioid nuisance in San Francisco is a substantial interference with public rights because it causes significant harm both to individuals and to the community. *See* paras. 8–9, *supra*.

IV. Walgreens’ Affirmative Conduct

A. Walgreens’ Conduct as a Distributor of Prescription Opioids

13. Walgreens engaged in wholesale distribution of prescription opioids in San Francisco as a DEA registrant.

13.1. Until 2014, Walgreens distributed prescription opioids to pharmacies it owned and operated. Lucas Fla. Test. 658:17–666:16; Polster Dep. 327:18–23.

13.2. The three facilities from which Walgreens distributed prescription opioids were located in Woodland, California (which distributed to Walgreens pharmacies in San Francisco); Jupiter, Florida; and Perrysburg, Ohio. Coman Trial Tr. at 695:25–696:14.

13.2.1. Because the Woodland facility distributed prescription opioids to San Francisco pharmacies, Woodland’s distribution practices bear directly on the opioid supply in San Francisco. The distribution practices of the Jupiter and Perrysburg facilities are relevant because those facilities were managed by the same employees as the Woodlands facility pursuant to uniform nation-wide corporate policies and procedures. *Cf.* Polster Decl. ¶ 6; P-08183_00001.

1 13.3. By law, in order to distribute prescription opioids, Walgreens was required
 2 to, and did, register with the DEA as a distributor. Walgreens held separate DEA
 3 registrations for each of its three distribution centers that handled controlled substances.
 4 See P-00035_00001, 00005 (DEA letters addressed to Walgreen Co. under two
 5 registration numbers for two different distribution centers).

6 13.4. As a distributor of prescription opioids, Walgreens was required to design
 7 and operate a system to identify “suspicious orders” of prescription opioids, and to refuse
 8 to ship orders of prescription opioids identified as suspicious until it was able to
 9 determine, through reasonable inquiry, that, if shipped, the order was not likely to be
 10 diverted outside the closed system. An order for controlled substances is suspicious if it is
 11 of unusual size or frequency, or if it substantially deviates from normal ordering patterns.
 12 Once identified, suspicious orders must be reported to the DEA. Rannazzisi Dep. 417:14–
 13 418:9, 419:14–21, 421:2–421:18; P-03669_00002; P-03670_00001.

14 13.4.1. Neither the CSA nor the DEA requires a *particular* suspicious order
 15 monitoring or “SOM” system at the distribution level. Rannazzisi Dep. 465:24–466:22; P-
 16 03670_00001. Registrants are free to design their systems in ways that make business
 17 sense for the registrant. But every SOM system must have a reasonable and good faith
 18 means to identify suspicious orders and those orders must be reported to the DEA.
 19 Rannazzisi Dep. 419:22–421:3. By contrast, a SOM system that does not take due care in
 20 identifying suspicious orders but instead simply turns a blind eye to suspicious
 21 circumstances is inadequate and does not satisfy a registrant’s obligations to design and
 22 operate a system for identifying and reporting suspicious orders. Rannazzisi Dep. 452:8–
 23 16; P-03669_00002.

24 13.4.2. In order to satisfy its obligation to maintain effective controls
 25 against diversion, a distributing registrant must not only identify and report suspicious
 26 orders, it must also halt shipment on those orders unless and until it has performed due
 27 diligence to determine that diversion is not likely. P-03669_00002; P-03670_00001.
 28

1 13.4.3. One critical aspect of maintaining a SOM system is a thorough
2 record of past opioids purchases. Indeed, the only way to detect patterns of orders over
3 time (as well as deviations from them) is to create and maintain a record of those orders.
4 Rannazzisi Dep. 647:7–19.

5 13.4.4. Around 2005, the DEA came to believe that the opioid supply
6 chain—specifically, manufacturers and distributors—was “out of control,” and that the
7 largest supply-chain actors were refusing to comply with their obligations as CSA
8 registrants to maintain effective controls against diversion. Rannazzisi Dep. 416:9–417:9,
9 423:12–426:4, 431:14–18. The DEA recognized that diversion and abuse of opioids,
10 specifically hydrocodone and oxycodone, had become a major public health crisis.
11 Rannazzisi Dep. 433:17–434:9; P-03669_00002.

12 13.4.5. To remind opioid supply-chain actors of their obligations under the
13 CSA, in 2006 the DEA sent letters to every commercial entity registered to distribute
14 controlled substances in the country. Rannazzisi Dep. 430:11–432:5; P-03669_00001.
15 The letters reminded manufacturers and distributors of what had always been the law
16 since the CSA was enacted in the 1970s: registrants are required in general to maintain
17 effective controls against diversion; registrants who distribute opioids (manufacturers and
18 distributors) are specifically required to create and maintain a SOM system, and to report
19 identified suspicious orders to the DEA; and registrants must not ship suspicious orders
20 until they have performed due diligence to determine that the order is not likely to be
21 suspicious. P-03669_00001 to 00002.

22 13.4.6. Walgreens received the 2006 letter from the DEA. *See* P-00035.

23 13.4.7. In 2007, the DEA sent a second letter to every entity registered to
24 manufacture or distribute controlled substances, to again remind the opioids supply chain
25 of its obligations to maintain effective controls against diversion, to maintain a SOM
26 system, to report suspicious orders to the DEA, and to investigate and not ship suspicious
27 orders until due diligence shows that diversion is not likely. Rannazzisi Dep. 464:1–466:8;
28 P-03670_00001.

13.4.8. Walgreens received the 2007 letter from the DEA. *See* P-27368.

14. Walgreens failed to maintain effective controls against prescription opioid diversion while distributing prescription opioids. *See* para. 27.3.1, *infra*.

14.1. Walgreens failed to create and maintain a system for detecting and reporting suspicious orders of prescription opioids.

14.1.1. Before 2012, Walgreens' SOM system was a virtual nullity.

14.1.1.1. Walgreens' employees repeatedly noted the absence of any meaningful SOM system. According to Walgreens' own internal audits from 2008, "there [was] no monitoring process in place to stop a suspicious order to assess if the order is suspicious or not." P-20656_00002.

14.1.1.2. To the extent it existed at all, Walgreens' SOM system was so disorganized and ineffective that no one at Walgreens seemed to know whose job it was to do the monitoring or if the monitoring was taking place.

14.1.1.2.1. In 2010, one Walgreens vice president for distribution (*see* P-28550_00001, P-25973_00001) wrote that he didn't know who, if anyone, had "been reviewing the [controlled substances order] data collected for the past twenty-five years?" P-00058_00001.

14.1.1.2.2. One of the Walgreens managers responsible on paper for Walgreens' national SOM system beginning in 2009, Barbara Martin, knew nothing about the regulatory framework governing Walgreens' SOM obligations and did not believe it was her job to know. Martin Dep. 23:20–24:3, 49:6–53:11, 60:1–127:8.

14.1.1.2.3. Walgreens did not provide Martin, the person supposedly overseeing its SOM programs, with critical information relating to that program, including monthly suspicious order reports (such as P-19720_00001 and P-19724_00001), the "average order times DEA factor" formula Walgreens used to flag orders as suspicious, or the "Chemical Handler" reports (which are Walgreens' own suspicious order reports). Martin Dep. 161:21–165:21.

14.1.1.2.4. Walgreens' corporate representative was unable to identify who was performing due diligence on orders flagged as suspicious. After the corporate representative identified employees who later said they were *not* performing this due diligence, Walgreens changed the answer of its representative to say that it was unaware of any due diligence performed on orders flagged as suspicious before 2012. P-20213_00004 (errata of corporate deponent). If due diligence had been performed on such orders, Walgreens would be aware of it.

14.1.1.3. Walgreens' SOM system was focused on ensuring that Walgreens did not flag too many prescription opioid orders as suspicious. Martin Dep. 24:1–24, 42:12–16, 42:20–22, 252:22–253:15.

14.1.1.4. Walgreens provided no training to its distribution center staff specific to the distribution of controlled substances. Lucas Fla. Test. 612:4–5, 615:19–23; Coman Trial Tr. 739:16–19; Ferry Dep. 39:15–25.

14.1.1.5. In 2010, Walgreens' Jupiter, Florida, distribution center began receiving orders for “unrealistic, astronomical” amounts of prescription opioids, increasing from 30 to 90 to 300 to 600 and more bottles of opioid pills per week. Lucas Fla. Test. 623:14–624:1, 625:12–20. Walgreens' corporate SOM system failed to report or arrest this trend. On the rare occasions when distribution center employees did “investigate” a suspicious order, they would simply call the Walgreens pharmacy placing the order to confirm the order had not been placed unintentionally. Lucas Fla. Test. 633:17–24.

14.1.2. In 2012, Walgreens implemented a new SOM system (then called “Controlled Substance Reporting” or “CSR”) that was in place until it stopped distributing prescription opioids in 2014. Though it appeared better on paper, the new system was, in fact, no more effective than the old one.

14.1.2.1. When Walgreens' new SOM system was activated for all controlled substances in 2012, 14,000 items that Walgreens' stores had ordered across the chain were flagged as needing investigation. P-00027_00001 to 00002. At that time,

1 Walgreens' Pharmaceutical Integrity unit had a staff of just ten employees. Polster Trial
2 Tr. 2395:05–2396:06.

3 14.1.2.2. The new SOM system imposed a “ceiling limit” on the
4 amount of any particular controlled substance that could be shipped to one store over a
5 rolling six-week period. Polster Trial Tr. 2269:02–08. Low “ceiling limits” resulted in
6 high numbers of ceiling override requests, likely resulting, in turn, in overburdening of
7 Walgreens staff tasked with approving or denying the requests. P-00059; Polster Trial Tr.
8 2388:09–2389:02, 2391:13–2392:02. As a result, in the two years during which the new
9 SOM system was operative, Walgreens approved 95 percent of controlled substance
10 override requests that were submitted to it. P-00062_00023; Polster Trial Tr. 2331:02–
11 2332:16.

12 14.2. Both before and after 2012, Walgreens shipped suspicious orders of
13 prescription opioids without determining through reasonable inquiry that filling the orders
14 would not likely result in prescription opioid diversion, in violation of its obligations
15 under the CSA.

16 14.2.1. According to Walgreens' own internal audits from 2008, Walgreens
17 was “filling orders that have been deemed suspicious without performing any research to
18 ascertain [their] legitimacy.” P-20657_00002. Walgreens also acknowledged that “there is
19 no monitoring process in place to prevent the fulfillment of an order if it has been deemed
20 suspicious.” P-20658 _ 00003 to 00004.

21 14.2.2. When Walgreens' Jupiter, Florida, distribution center began
22 receiving orders for exceptionally high volumes of prescription opioids, a manager at the
23 distribution center alerted her corporate superiors, but Walgreens conducted no
24 investigation. Lucas Fla. Test. 623:14–624:1, 625:12–20, 628:2–25, 635:15–18.
25 Walgreens pharmacists at the stores served by the Jupiter center confirmed that they were
26 not performing due diligence on their part either. Catizone Decl. ¶ 37; Lucas Fla. Test.
27 631:18–632:14. Unless the ordering store disclosed that it had placed an order
28

1 unintentionally by mistake, the orders were filled and shipped. Lucas Fla. Test. 633:17–
2 24, 634:4–15.

3 14.2.3. The DEA shut down Walgreens’ distribution of Schedule II
4 controlled substances from the Jupiter distribution center in 2012 for multiple CSA
5 violations that endangered the public health. P-00015_00028.

6 14.2.4. According to an internal audit from Walgreens’ Woodland,
7 California, distribution center in 2008, from which Walgreens distributed prescription
8 opioids to Walgreens pharmacies in San Francisco, “Walgreens is filling orders that have
9 been deemed suspicious without performing any research to ascertain the legitimacy of
10 the order.” P-20657_00002.

11 14.2.5. According to Walgreens’ own internal audit completed in 2011,
12 Walgreens’ Woodland, California, distribution center was still filling suspicious orders
13 without due diligence three years later. P-27384_00022; Coman Trial Tr. 731:13–15,
14 738:14–739:8, 739:16–19.

15 14.2.6. The Walgreens manager in charge of the Woodland, California,
16 distribution center did not know what criteria were used to identify suspicious orders, nor
17 whether Walgreens had a duty to report those orders to the DEA before shipment, nor
18 whether Walgreens had ever done so. Coman Trial Tr. 695:10–13, 705:22–706:7, 708:23–
19 709:5. When showed an excerpt of the sections of a Walgreens suspicious order report
20 from 2008 covering San Francisco, the manager admitted that he did not know how often
21 such reports were generated or reviewed by Walgreens staff. Coman Trial Tr. 716:4–11,
22 716:14–17. The only Walgreens employee the manager was aware of who may have been
23 reviewing these extensive suspicious order reports was Juanita Gonzalez, who may have
24 been doing so for one to two hours a week. Coman Trial Tr. 716:14–717:1, 720:13–22.
25 No one in Walgreens’ corporate offices or computer room provided her with any support.
26 Coman Trial Tr. 749:24–750:3, 752:23–753:2. It is reasonable to infer that, if Walgreens
27 had ever investigated suspicious orders before filling them from the Woodland center, this
28 manager would have known about it. According to Walgreens’ own testimony, suspicious

1 order monitoring was supposed to be conducted “at the distribution level.” Polster Tr.
2 2346:3–22; *see also* Polster Decl. ¶ 6.

3 14.2.7. The Walgreens manager in charge of the Woodland, California,
4 distribution center did not recall (but likely would have, had it happened) that Walgreens
5 ever trained its employees on “how to use ... suspicious order report[s],” “perform due
6 diligence,” or “analyze patterns or frequency” of orders. Coman Trial Tr. 739:9–740:9.

7 14.2.8. According to the Walgreens manager in charge of the Woodland,
8 California, distribution center, Walgreens did not devote enough resources to perform due
9 diligence on suspicious orders. Coman Trial Tr. 741:19–742:1. It is therefore more likely
10 than not that it was not performed.

11 **B. Walgreens’ Conduct as a Dispenser of Prescription Opioids**

12 **15.** Walgreens dispensed prescription opioids in and around San Francisco as a
13 DEA registrant subject to the standards of pharmacy practice in California.

14 15.1. As of December 31, 2021, Walgreens owned and operated 53 pharmacies
15 in San Francisco. Brunner Decl. ¶ 31.

16 15.2. Walgreens holds separate DEA registrations for each of its pharmacies in
17 San Francisco. *See* P-00015_00006 (stipulating Walgreens would surrender six DEA
18 registrations for six different pharmacies); Catizone Trial Tr. 796:14–15.

19 15.3. As a DEA-registered dispenser, Walgreens was required to maintain
20 effective controls against diversion in its dispensing of prescription opioids. Moreover,
21 under the CSA, pharmacists, pharmacies and pharmacy owners are authorized to dispense
22 only prescriptions that have been issued for a legitimate medical purpose by individual
23 practitioners acting in the usual course of their professional practice. *See* para. 27.3.1,
24 *infra*.

25 15.3.1. A prescription written for a legitimate medical purpose is a
26 prescription intended by both the prescriber and the patient for good faith medical use. A
27 prescription may be illegitimate because the prescriber is not attempting to offer good
28 faith medical treatment in the usual course of professional practice, or because the patient,

1 with or without the prescriber's knowledge, does not intend to use the prescription as
 2 directed for the good faith treatment of the medical condition for which it was prescribed.
 3 *Cf.* para. 5.2.2.4, *supra*.

4 15.4. Pharmacists, pharmacies, and pharmacy owners are each responsible for
 5 the proper practice of pharmacy; the responsibility is not the pharmacist's alone. *See*
 6 Catizone Decl. ¶¶ 13–14; Catizone Trial Tr. 796:13–797:6; Park Decl. ¶ 5.

7 **1. Red Flags of Diversion: Due Diligence Standards**

8 15.5. Under the standard of pharmacy practice prevailing in California and
 9 across the country, there are four elements of due diligence in opioid dispensing:
 10 *identification* of all “red flags” of diversion; *collection* of all relevant information;
 11 *evaluation* of the information; and *documentation* of the reasons supporting the decision
 12 to dispense or not. Catizone Decl. ¶ 24; Park Decl. ¶¶ 7, 10; Park Trial Tr. 962:11–23; P-
 13 29955_00004.

14 15.6. The prevailing standard of pharmacy practice in California, and across the
 15 country, calls for dispensers to look for and recognize indications that an opioid (or any
 16 controlled substance) prescription is likely to be diverted. These indications are commonly
 17 called “red flags.” *See* Catizone Decl. ¶ 17; Park Decl. ¶¶ 8–9; P-42147_00003 to 00007
 18 (*Holiday CVS*); Ashley Dep. 121:11–19.

19 15.6.1. Red flags are objective warning signs that may indicate that
 20 activities are occurring outside the usual and customary scope of pharmacy practice—
 21 activities that are suggestive of abuse, diversion, and fraudulent acts. Catizone Decl. ¶ 16;
 22 Rannazzisi Dep. 1576:23–1577:22; Park Decl. ¶¶ 7–9; Park Trial Tr. 962:11–23. Red
 23 flags are a nationally recognized concept in the practice of pharmacy, acknowledged by
 24 the DEA, state boards of pharmacy, professional associations, and industry trade groups.
 25 *See* Catizone Decl. ¶ 17; Park Decl. ¶¶ 8–9; P-23068 (2015 NABP stakeholder report); P-
 26 42147_00003 to 00007 (*Holiday CVS*); Ashley Dep. 121:11–19.

27 15.6.2. While there is no fixed and exhaustive catalogue of red flags, eight
 28 commonly occurring situations are generally recognized in California, and across the

country, as prompts for further inquiry. *See* Catizone Trial Tr. 799:13–800:21 (citing national supports for identified red flags); Catizone Decl. ¶ 19 n.12 (same); Park Decl. ¶ 17 (affirming red flags recognized in California); Park Trial Tr. 961:21–25 (same).

15.6.2.1. *Long-distance travel.* Patients traveling long distances to their pharmacies or physicians raises a red flag as potentially unreasonable or evasive behavior. Catizone Decl. ¶ 18; Catizone Trial Tr. 868:2–12 (discussing P-23068_00016); P-23068_00015 (2015 NABP stakeholder report); P-15314_00027 (mid-2012 GFD policy establishing “unusual geographic distances” as red flag); P-17169_00010 to 00011 (late 2013 GFD training presentation acknowledging “prescriber located outside of the pharmacy’s trade area” and “[patient] resides outside of the trade area of your pharmacy” as red flags); WAG-MDL-03398.00002 (publication from California Board of Pharmacy outlining corresponding responsibility).

15.6.2.2. *Doctor shopping.* A patient receiving concurrent opioid prescriptions from different prescribers, or “doctor shopping,” raises a red flag that the patient may be soliciting duplicative prescriptions. Catizone Decl. ¶ 18; Catizone Trial Tr. 801:25–802:8, 831:9–20; P-23068_00014 (2015 NABP stakeholder report); P-15314_00028 (mid-2012 GFD policy establishing “prescriptions from several different prescribers” as red flag); P-17169_00011 (late 2013 GFD training presentation acknowledging “doctor shopping” as red flag); WAG-MDL-03398.00002 (California Board of Pharmacy corresponding responsibility outline).

15.6.2.3. *Pharmacy shopping.* A patient having concurrent opioid prescriptions filled at different pharmacies, or “pharmacy shopping,” raises a red flag for similar reasons as doctor shopping. Catizone Decl. ¶ 18; P-23068_00015 (2015 NABP stakeholder report); P-17169_00011 (late 2013 GFD training presentation acknowledging “pharmacy shopping” as red flag).

15.6.2.4. *Drug cocktails.* A patient presenting prescriptions for “cocktails” of drugs consisting of opioids and benzodiazepines (like Valium or Xanax) with or without muscle relaxants (like Soma) raises a red flag because these drugs are

1 particularly dangerous in combination and are commonly abused together. Catizone Decl.
 2 ¶ 18; Catizone Trial Tr. 834:11–835:4; P-23068_00014 (2015 NABP stakeholder report);
 3 P-15314_00027 (mid-2012 GFD policy establishing “known drug ‘cocktails’ such as a
 4 benzodiazepine, opioid and carisoprodol” as red flag); *see also* P-17169_00012 (late 2013
 5 GFD training presentation acknowledging “cocktail[s] of commonly abused drugs” as red
 6 flag).

7 15.6.2.5. *Excessive dispensing.* A patient presenting one or more
 8 prescriptions for excessive quantities of opioids raises a red flag because it is unlikely
 9 such excessive quantities would be prescribed for legitimate medical purposes. *See*
 10 Catizone Decl. ¶ 18; P-15314_00027 (mid-2012 GFD policy establishing “[u]nusual
 11 dosages” or “quantities ... beyond those normally prescribed” as red flag); P-17169_00012
 12 (late 2013 GFD training presentation acknowledging “unusually large quantity or high
 13 starting dose” as red flag); WAG-MDL-03398.00002 (California Board of Pharmacy
 14 corresponding responsibility outline: “prescriptions written for an unusually large quantity
 15 of drugs”).

16 15.6.2.6. *Pattern prescribing.* A patient filling a prescription from a
 17 “pattern prescriber,” or a prescriber who writes prescriptions for the same drug at the
 18 same dose and duration for large numbers of patients, raises a red flag because it suggests
 19 the absence of individualized examination or treatment, or a failure to exercise medical
 20 judgment. *See* Catizone Decl. ¶ 18; P-17169_00010 (late 2013 GFD training presentation
 21 acknowledging “same diagnosis for the majority of individuals” as red flag); WAG-MDL-
 22 03398.00002 (California Board of Pharmacy corresponding responsibility outline: “same
 23 combinations of drugs prescribed for multiple patients”).

24 15.6.2.7. *Early refills.* A patient refilling a prescription early raises a
 25 red flag because it suggests a failure to take the drugs at the dosages and durations
 26 prescribed, or “non-adherence” to the prescriber’s treatment plan. Catizone Decl. ¶ 18; P-
 27 23068_00015 (2015 NABP stakeholder report); P-15314_00028 (mid-2012 GFD policy
 28 establishing “[c]onstistently request[ing] early refills” as red flag); P-17169_00011 (late

1 2013 GFD training presentation acknowledging “routine[] attempts to obtain an early
2 refill” as red flag); WAG-MDL-03398.00002 (California Board of Pharmacy
3 corresponding responsibility outline).

4 15.6.2.8. *Cash payment.* A patient paying cash for opioids raises a red
5 flag as potentially evasive behavior. Catizone Decl. ¶ 18; P-23068_00016 (2015 NABP
6 stakeholder report); P-15314_00028 (mid-2012 GFD policy establishing “[r]equest[s] to
7 pay by cash or by using a cash discount card” as red flag); P-17169_00011 (late 2013
8 GFD training presentation acknowledging “pay[ing] cash, or insist[ing on] paying cash for
9 controlled substances even though insurance is on file” as red flag); WAG-MDL-
10 03398.00002. Between 90 to 95 percent of pharmacy claims are paid by private insurance
11 or public programs. Catizone Trial Tr. 838:4–15.

12 15.7. The prevailing standard of pharmacy practice in California, and across the
13 country, is to treat red flags as triggering the necessity for further inquiry. Unless such
14 further inquiry as is reasonable under the circumstances determines that diversion is
15 unlikely, the prescription should not be dispensed. Catizone Decl. ¶¶ 23–27; Park Decl.
16 ¶¶ 7–8; P-15314_00029 (mid-2012 GFD policy prohibiting dispensing if pharmacist is
17 “unable to satisfy the elements of good faith,” that is, unable to resolve red flags raised by
18 prescription).

19 15.8. The prevailing standard of pharmacy practice in California, and across the
20 country, is to reasonably document why a red-flagged prescription was or was not
21 dispensed after investigation. Catizone Decl. ¶¶ 25–26; Park Decl. ¶¶ 10–12; P-
22 29955_00004 (California Pharmacists Association “Corresponding Responsibility
23 Checklist”) (“The pharmacist must document every resolution and non-resolution.”); Nip
24 Dep. 30:9 (California Board of Pharmacy employee: “industr[y] standard” is
25 “documenting” red flag resolution).

26 15.8.1. Reasonable due diligence shows the pharmacist’s work and explains
27 the red flags identified, the information evaluated in resolving them, and the ultimate
28

1 reasons for dispensing. Catizone Decl. ¶ 26; *see also* Nip Dep. 30:21–22 (“the why, who,
2 when, what, and how”).

3 15.8.2. Documentation is critical because it explains how the pharmacist
4 resolved red flags or why the pharmacist refused to fill the prescription so that the same or
5 other pharmacists can make use of the information when filling future prescriptions from
6 the same doctor or the same patient. Catizone Trial Tr. 802:13–17. Documentation also
7 affords the pharmacy the opportunity to review, audit, and investigate whether red flags
8 are being identified and appropriately resolved, and it assists regulators if there is a need
9 to investigate potential diversion. Catizone Decl. ¶ 25; Park Decl. ¶ 11.

10 15.8.3. It is a basic tenet of pharmacy practice that, “if you didn’t document
11 it, it didn’t happen.” Gayle Dep. 51:21–52:5; *see also* Nip Dep. 30:22–23 (“[I]f it’s not
12 documented, it’s not considered done.”); Park Decl. ¶ 10; Mathews-Porter Dep. 72:2–19.
13 If a red flag is resolved without documentation, “for all practical purposes, the resolution
14 didn’t occur.” Catizone Trial Tr. 802:13–17. *See also* P-17247_00004 (Walgreens
15 presentation on “drug utilization review” or “DUR” requiring “[d]ocumentation of actions
16 performed when resolving a DUR” because “[d]ocumentation allows anyone to know
17 what you, the pharmacist, was [*sic*] thinking of at the time of fill”).

18 15.8.4. Walgreens’ written policies beginning in 2012 reflect the prevailing
19 standard of pharmacy practice and require documentation of red flag resolution. Catizone
20 Decl. ¶¶ 46–47; Park Decl. ¶ 13–14; P-15314_00028 (mid-2012 GFD policy stating, “It is
21 imperative that pharmacists document all efforts used to validate good faith dispensing,”
22 that is, to investigate and resolve red flags); P-15074_00005 (mid-2016 GFD policy
23 stating same); Polster Dep. 25:19–26:16; Stahmann Dep. 97:8–98:1; Gayle Dep. 50:8–10.

24 15.8.5. Walgreens suggests that documentation of due diligence is not the
25 prevailing professional standard or part of the standard of care in California, pointing to
26 evidence that the outpatient pharmacy at ZSFG has no written policy requiring it. The
27 Court rejects this view of the evidence.
28

15.8.5.1. The Court finds credible the testimony of the People’s experts Carmen Catizone and Elizabeth Park that documentation is part of the standard of care for retail pharmacies in California. Catizone Decl. ¶¶ 25–26; Park Decl. ¶¶ 10–12. As the former executive director and CEO of the NABP, and as a practicing regulatory and compliance pharmacist in California, respectively, Mr. Catizone and Dr. Park are in a position to know what the standard is. The Court finds the other evidence cited above likewise credible. *See, e.g.*, P-29955_00004 (California Pharmacists Association “Corresponding Responsibility Checklist”).

15.8.5.2. Credible testimony demonstrates that the policy of the outpatient pharmacy at ZSFG reflects the prevailing standards and requires documentation of red flag resolution. Although this policy is not codified in a written document, staff are informed of their obligations under this policy by the director of pharmacy. *See* Patel Trial Tr. 1310:16–23, 1340:2–13, 1346:1–1348:3.

15.8.5.3. While the policy of DPH as a whole does not contain a documentation requirement, *see* D. Woods Dep. 74:13–21, that absence reflects the unique circumstances of City-operated pharmacies—which include in-patient pharmacies, jail pharmacies, and skilled nursing facility pharmacies—in which pharmacists have access to a complete “closed medical record,” including the physician’s notes. D. Woods Dep. 70:2–16.

15.8.5.4. The fact that Walgreens’ own written policies require documentation further supports the inference that documentation is part of the prevailing professional standard.

15.9. The prevailing standard of pharmacy practice in California is for a pharmacy to comply with its own policies and procedures. Park Decl. ¶ 6.

2. Walgreens’ Dispensing Policies and Practices

16. Walgreens failed to maintain effective controls against diversion, failed to ensure that it dispensed prescription opioids only for legitimate medical purposes, and

1 failed to comply with prevailing standards of pharmacy practice in dispensing opioids.

2 *See* para. 27.3.1, *infra*.

3 16.1. Walgreens’ written policies were insufficient to ensure that Walgreens
4 pharmacies and pharmacists performed and documented the due diligence necessary to
5 ensure that opioid prescriptions were dispensed only for legitimate medical purposes.

6 16.1.1. From 2003 to 2012, Walgreens’ written “Good Faith Dispensing”
7 policy, which governed the circumstance where a pharmacist detected a red flag, was
8 simply an instruction to call the prescriber. If the prescriber stated that the prescription
9 was valid, pharmacists were expected to “process the prescription as normal.” P-
10 15119_00012 (June 2006). A Walgreens pharmacist following this policy would be
11 incapable of identifying doctors who were not prescribing for legitimate medical purposes
12 or who had been duped by patients intending to divert the prescription to non-medical use.

13 16.1.1.1. The Court does not credit evidence that this was not in fact
14 Walgreens’ policy from 2003 to 2012. Contemporaneous documentation shows that the
15 2012 policy rewrite was a “game ... change[r]”: “[W]e can no longer rely on the ‘I spoke
16 to the prescriber and he said it was okay.’ This is especially true when the prescriber may
17 be assisting the patient to inappropriately use controlled substances.” P-20639_00009
18 (presentation by Tasha Polster). The clear inference is that, before 2012, Walgreens
19 instructed its pharmacists they could dispense controlled substances as long as the doctors
20 “said it was okay.” P-20639_00009.

21 16.1.2. Walgreens’ 2003–2012 “call the prescriber” policy was recognized
22 by Walgreens itself as inadequate in 2012. P-20639_00009.

23 16.1.3. After paying \$80 million to the DEA to settle allegations of CSA
24 violations in 2013, P-00015_00007, beginning in April 2013 Walgreens created a “Target
25 Drug Good Faith Dispensing” policy that required completion of a checklist of due
26 diligence tasks for certain covered (“target”) drugs. But the checklist policy covered only
27 three single-ingredient prescription opioids and excluded commonly abused opioid drugs
28 like Percocet (an oxycodone/acetaminophen combination), Norco (a

1 hydrocodone/acetaminophen combination), and Vicodin (same). P-00015_00007;
2 Catizone Decl. ¶ 43. It also excluded single-ingredient hydrocodone, which was the
3 “number one prescribed, dispensed, and abused drug in the United States.” Catizone Trial
4 Tr. 810:12–811:6.

5 16.1.3.1. From 2006 to 2020, approximately 391 million opioid dosage
6 units dispensed by Walgreens, or 63.3 percent of the total in the Bay Area, were
7 comprised of drugs that were not covered by the TDGFD policy. For San Francisco itself,
8 approximately 89 million dosage units dispensed by Walgreens, 57 percent of the total,
9 were comprised of drugs that were not covered by the TDGFD policy. *See* P-
10 29837_00002.

11 16.1.3.2. In both the Bay Area and San Francisco, hydrocodone
12 products accounted for the largest proportion of all opioid drugs dispensed by Walgreens
13 between 2006 and 2020 (61.8 and 49.1 percent, respectively). *See* P-29837_00002.

14 16.1.4. Walgreens’ record-keeping policies and practices frustrated its
15 TDGFD checklist policy.

16 16.1.4.1. Until 2019, the checklists were not digitized and were
17 maintained in a way that made them difficult to access within a single store, and nearly
18 impossible to review across Walgreens’ many pharmacies. Catizone Decl. ¶¶ 44–47.

19 16.1.4.2. When the checklist was finally made electronic in late 2019,
20 Tasha Polster acknowledged that the improvement should have been “from day one” but
21 had earlier been vetoed by Walgreens executives. P-20795_00001. The result was that, for
22 years, due diligence documented by one pharmacist—including, for example, concerns
23 about a particular prescriber or patient—could not be effectively used to protect against
24 future diversion.

25 16.2. Walgreens’ business practices created incentives to dispense prescription
26 opioids without delay, and discouraged performing and documenting due diligence
27 necessary to ensure that opioid prescriptions were dispensed only for legitimate medical
28 purposes.

1 16.2.1. Walgreens understaffed its pharmacies in San Francisco relative to
2 the time and effort reasonably required to responsibly dispense the volume of
3 prescriptions presented to those pharmacies.

4 16.2.1.1. One San Francisco Walgreens pharmacy filled between 200
5 and 300 prescriptions per day with only one pharmacist on duty for all but two to three
6 hours of the day. Lo Decl. ¶ 5. By contrast, the outpatient pharmacy at Zuckerberg San
7 Francisco General Hospital fills 250 to 300 prescriptions per day with seven pharmacists
8 on staff (and 11 additional support staff). Patel Trial Tr. 1292:20–1293:3, 1299:10–12,
9 1332:23–24.

10 16.2.1.2. One Walgreens pharmacist in San Francisco, as a new
11 pharmacist just out of pharmacy school, was the only pharmacist on duty at his Walgreens
12 pharmacy “easily 75 percent” of the time, and about 25 percent of the time did not even
13 have the assistance of a pharmacy technician. Gerspacher Dep. 25:24–26:4, 26:13–25,
14 27:3–9.

15 16.2.1.3. According to Walgreens’ corporate executives in February
16 2013, whose reports the Court credits on this point, “Fatigue and sustainability of our
17 pharmacists is a real concern. We’re asking them to do a lot but how long can they
18 continue?” P-27333_00002; *see also* P-17218_00001, 00005 (Walgreens pharmacists
19 were “struggling to keep our heads above water let alone manage,” and executive heard
20 these concerns “loud and clear in San Francisco” in May 2013).

21 16.2.1.4. According to Walgreens pharmacists, whose reports the
22 Court credits on this point, understaffing and overwork were common at Walgreens
23 pharmacies. *See* Gayle Dep. 21:8–11; Yagar Dep. 50:19–20; Lo Trial Tr. 918:17–919:4,
24 920:4–8; Kamali Dep. 62:5–6, 62:24–63:3.

25 16.2.2. Just after promulgating its “Target Drug Good Faith Dispensing”
26 policy in 2013, Walgreens instructed its field leadership that due diligence obligations
27 would not excuse failure to achieve the sales targets set by Walgreens. P-00060_00002
28

1 (“[Good Faith Dispensing] concerns do[]n’t relieve you from trying to attain the numbers
2 that have been set for you.”).

3 16.2.3. Walgreens’ policies encouraged its pharmacists to work at unsafe
4 speeds by several means, including a color-coded tool called a “PhLOmometer” that
5 encouraged pharmacists in real time to fill prescriptions faster, and paying bonuses based
6 on the number of prescriptions filled. Catizone Decl. ¶¶ 65–66 (discussing P-
7 23078_00002; P-19821_00001; P-19529_00001).

8 16.2.3.1. A pharmacist pressured to work too quickly is at risk of
9 missing red flags and is discouraged from investigating any red flags she does identify.
10 Catizone Decl. ¶ 63.

11 16.2.3.2. Through interviews with a third-party consultancy,
12 Walgreens pharmacists informed Walgreens that “improper behavior” by pharmacists was
13 “largely attributed to the desire” to meet a Walgreens prescription dispensing speed metric
14 known as “promise time,” that is, the time within which patients are promised to get their
15 prescriptions filled. P-14357_00037. But Walgreens did nothing to remove this spur to
16 “improper behavior,” and indeed instructed the consultancy to omit further mention of it.
17 P-14370_00039.

18 16.2.4. Walgreens pharmacists understood that Walgreens expected them to
19 prioritize filling prescriptions above all other concerns. Gayle Dep. 16:25–17:4 (“[T]he
20 most challenging part of working at Walgreens was I constantly felt like there was a
21 pressure to fill, fill, fill and that was what the company cared about most, was the message
22 I got.”); Lo Trial Tr. 918:17–19 (“Everything was about numbers, always. ... Verify by
23 promise time, wait times, phone times, how many—how many seconds, literally
24 seconds.”). The Court credits the testimony of one Walgreens pharmacist, Victor Lo, who
25 testified that his pharmacy supervisor pressured him to fill controlled substances
26 prescriptions. When confronted with the testimony, the supervisor initially denied Lo’s
27 account, but later admitted that what Lo described did “sound like something [she] would
28 say.” Lowe Tr. 3088:9–13.

1 16.2.5. Walgreens pharmacists repeatedly complained to Walgreens that
 2 Walgreens’ business practices interfered with pharmacists’ ability to properly dispense
 3 opioid prescriptions and maintain patient safety. The Court credits these complaints as
 4 descriptions of the working environment common at Walgreens pharmacies in light of the
 5 complaining pharmacists’ strong incentives to keep quiet, and in light of the national
 6 scope of Walgreens corporate policies and programs about which the pharmacists
 7 complained. *Cf.* P-27287_00005 (“Most [Walgreens pharmacists] just go ahead and fill
 8 recklessly because they don’t want to be hassled with the consequences, have their hours
 9 reduced, scheduled to work far from their home, or [be] blacklisted.”).

10 16.2.5.1. Walgreens’ internal complaint database (called “APIS”)
 11 shows that Walgreens’ pharmacists have perennially complained that short-staffing,
 12 speed- and volume-based performance metrics, and pressure from managers to maintain
 13 customer satisfaction have impeded pharmacists’ ability to conduct due diligence on
 14 opioid prescriptions. Catizone Decl. ¶¶ 32–34; *see also* P-27295_00002 (“We are putting
 15 profits above the safety of our customers. When Ford and Boeing did that it did not pay
 16 off. I hope Walgreens will do what is right/ethical and remove this metric immediately
 17 before lives are lost and litigation ruins this great company.”); P-27288_00002 (“Staff is
 18 being pressured to fill all narcotic prescriptions by pharmacy manager.”); P-27297_00002
 19 (Pharmacist felt “pressured to fill prescription[s]” from a doctor “running a pill mill.”); P-
 20 27303_00002 (“[The supervisor] attempted to convince her that she should just dispense
 21 the prescription to the patient AGAINST HER PROFESSIONAL JUDGMENT.”); P-
 22 27300_00002 (Pharmacy manager “again insisted the GFD policy does not apply to his
 23 store. ... Dispensing medications ASAP was the company’s priority.”); P-27305_00002
 24 (“The pharmacist “explained that Store Manager ... and Pharmacy Manager ... receive a
 25 bigger bonus if they have prescription sales. ... [The complainant] feels pressured by [the
 26 manager] because they want her to fill narcotic prescriptions without verification first.”);
 27 P-27298_00003 (Store manager “overrode and removed his decision not to dispense a
 28 prescription to a customer.... [The manager] told him that she could not afford to lose a

customer who spends \$6,000 a month in her store.”); P-27327_00003 (“The lack of adequate staffing pos[es] risks to patient safety and standards of customer service.”); P-27296_00002 (“Pharmacy Manager ... has been bypassing safety checks with the customer’s prescriptions ... to meet the promise time.”).

16.2.6. Walgreens’ corporate policy was to “not for an extended period of time block a prescriber that had an active DEA and state license,” Stahmann Dep. 14:1–6, 134:3–06, “[r]egardless of [the] prescriber’s prescribing history.” P-25638_00001 (emphasis added). Compare Mathews-Porter Dep. 106:16-107:02 (discussing the “Rite Aid system, where they just black out the doctor completely so you could not fill for him”). This was the policy up and until a prescriber’s license was revoked. Polster Trial Tr. 2305:01–2306:01 (short of license revocation, “[i]f [a prescriber’s] office was indeed raided, it was completely shut down, we *may potentially* block their prescriptions from being filled” (emphasis added)). By refusing to block suspicious opioid prescribers writing prescriptions that were likely to be diverted from using its pharmacies chain-wide, Walgreens needlessly saddled its pharmacists with the burden of having to investigate afresh each prescription written by such prescribers. Lo Decl. ¶¶ 16, 18–20.

16.2.7. Purportedly to protect prescribers’ reputations, Walgreens instructed its pharmacists not to write anything negative about prescribers in its electronic records, and often deleted comments indicating a prescriber’s prescriptions would likely be diverted. Lo Decl. ¶¶ 16, 18–20; Yagar Dep. 103:02-19, 104:18-105:12; Kamali Dep. 69:13-70:21; P-27332_00001 (“[P]lease note the comment of ‘Candy Doc’ has been removed from all prescriber profiles.”); P-17229_00001 (“Any comments such as ‘prescriber under investigation’ in the prescriber’s profile should be removed.”); P-25638_00001 (“[P]lease advise the pharmacy staff to refrain from entering any slanderous comments in the prescriber’s IC+ profile and stick with generic comments such as ‘verify GFD’.”).

16.2.8. Walgreens failed to provide any mechanism for its pharmacists to effectively communicate their concerns about potentially illegitimate prescribers to other

1 pharmacies and pharmacists. Lo Decl. ¶¶ 16-19 (“Even when suspicious prescribers were
 2 identified, Walgreens offered no effective way to spread that information.”); Gayle
 3 Dep. 89:22-90:15, 101:24-102:5 (testifying that she tried to warn other pharmacists in her
 4 neighborhood but had no tools of formal system to share her concerns more broadly).

5 16.2.9. Walgreens had in its possession detailed data, collected from its
 6 pharmacies and purchased from vendors, about the doctors whose prescriptions it
 7 dispensed, and the patients to whom those prescriptions were dispensed. Walgreens could
 8 have but failed to use this data to aid its pharmacies’ due diligence efforts, and purposely
 9 withheld this data from its pharmacists.

10 16.2.9.1. Walgreens possessed a vast amount of dispensing data and
 11 other information collected from its individual pharmacies. Walgreens also had robust
 12 data sets from vendors such as IQVIA/IMS, LexisNexis, and Medispan. Catizone Decl.
 13 ¶ 53; P-28445_00008 to 00009.

14 16.2.9.2. Walgreens used data in its possession to compile “prescriber
 15 indexes” or “prescriber potential risk indexes” to rank prescribers based on risk factors
 16 such as total opioid volume and average pills per prescription; percentage of prescriptions
 17 that are opioids; percent of opioid patients that pay cash; percent of prescriptions filled out
 18 of state; and sudden increases in these trends. *See* P-27367 (2013 Ed Bratton e-mail
 19 explaining index); P-06999a (2012 presentation explaining index); P-27369a (spreadsheet
 20 of indexed prescribers).

21 16.2.9.3. Walgreens’ executives made the decision to withhold this
 22 information from its pharmacists out of concern that pharmacists would decline to fill
 23 prescriptions written by the suspicious doctors it had identified. A Walgreens executive
 24 admitted that Walgreens had this information and withheld it, explaining that Walgreens
 25 did not want to “cloud the judgment” of its pharmacists. Stahmann Dep. 68:13–16,
 26 130:18–21, 130:24, 131:2–13; Polster Trial Tr. 2306:23–2307:06.

27
 28

16.2.9.4. The Court credits the testimony of Walgreens’ pharmacists that they would have liked to have this kind of information and that it would have made a difference in their ability to perform appropriate due diligence.

16.2.9.4.1. Rebecca Gayle wanted, but never received, lists of prescribers warranting extra scrutiny. This kind of data would have allowed her to identify outlier physicians and conduct additional due diligence. This information “could have avoided” the dispensing of illegitimate prescriptions. Gayle Dep. 67:17–69:12, 71:22–72:14, 87:04–90:15.

16.2.9.4.2. Robert Yagar wished Walgreens had a way of identifying bad prescribers and pill mills. In the absence of such a system, Yagar tried to maintain a personal list of suspicious prescribers. Yagar Dep. 102:18–103:1.

16.2.9.4.3. Christy Mathews-Porter testified that she would have liked data on “heavy prescribers” and would have used the information to as a red flag to be investigated. Mathews-Porter Dep. 111:1–12.

16.2.9.5. Walgreens could have been analyzing that data to identify dispensing and prescribing trends, among other things, and using that information to strengthen its controls against diversion. Keller Decl. ¶¶ 29–30 (IQVIA data); Catizone Decl. ¶¶ 55–62 (citing among others P-25699_00001; P-19543_00001; P-17193; P-19690; P-28445_00010 to 00012; P-25700_00018 to 00023; P-25700_00018 to 00019; P-28445_00010 to 00012; P-28446_00009 to 00010; P-19607_00002; P-15315_00009 to 00014; P-25503; P-19573_00007).

16.3. Walgreens expressly and impliedly communicated an inaccurate picture of opioids’ risks and benefits to its pharmacists, so that its pharmacists were less wary of opioid dispensing than they would have been otherwise.

16.3.1. In 1998, Walgreens began to seek out Purdue’s speakers to train Walgreens’ pharmacists on opioids and pain management through continuing education (CE) programs that sought to reduce barriers pharmacists might pose to filling opioids prescriptions. Lembke Decl. ¶ 117; P-25983; P-25984; P-25985; Perri Decl. ¶ 112; Perri

1 Trial Tr. 1836:4-14. One such CE was prepared by Purdue-paid “key opinion leader”
 2 Arthur Lipman. Lembke Decl. ¶ 117; P-27120_00033 to _00034; P-27170; P-27169; P-
 3 27020 (Lipman CE); Perri Decl. ¶ 116. The Lipman CE, “The Use of Opioids in Chronic
 4 Noncancer Pain,” instructed pharmacists that addiction among pain patients was
 5 “exquisitely rare.” Lembke Decl. ¶ 117; P-27038_00005, P-27038_00014; Lembke Trial
 6 Tr. 396:18–23. It also claimed that “[p]seudoaddiction is appropriate drug seeking
 7 behavior for the purpose of comfort, not abuse”; and “[p]seudoaddiction can be
 8 differentiated from drug misuse by increasing the dose by an appropriate amount and
 9 determining if the complaints abate.” P-27020_00008 to 00009; Perri Decl. ¶¶ 116-17;
 10 Lembke Decl. ¶ 117; Lembke Trial Tr. 405:16-406:04.

11 16.3.2. Walgreens argued that these claims were consistent with the FDA-
 12 approved label for OxyContin, which until July 2001 stated that “iatrogenic ‘addiction’ to
 13 opioids legitimately used in the management of pain is very rare.” In July 2001, however,
 14 the FDA-approved label was changed to eliminate the foregoing text and, instead, read as
 15 follows: “The development of addiction to opioid analgesics in properly managed patients
 16 with pain has been reported to be rare. However, data are not available to establish the
 17 true incidence of addiction in chronic pain patients.” The Lipman CE materials remained
 18 effective until 2002, however, and there is no evidence in this case that Walgreens
 19 educated its pharmacists to correct the misinformation that addiction among pain patients
 20 was indeed “exquisitely rare.” P-27020_00002, 00008; DEF-MDL-13160; *see* Lembke
 21 Trial Tr. 1082:10–13.

22 16.3.3. Walgreens repeatedly requested the Lipman CE from Purdue. Perri
 23 Decl. ¶ 118; Lembke Decl. ¶ 118; P-27221; P-27169; P-27170. Walgreens noted the
 24 importance of having “well-informed pharmacists in the area of pain management.”
 25 Lembke Decl. ¶ 118; P-26062_00003. Dr. Lipman’s CE programs increased pharmacy
 26 sales of OxyContin dramatically.

27 16.3.4. The Lipman CE was rolled out in Wisconsin, Florida, Tennessee,
 28 Utah, and Chicago. The CE is an example of a national campaign of Walgreens training

1 material. Such training was uniform to Walgreens’ pharmacists all over the country,
2 which affects California. Lembke Trial Tr. 1069:24–1071:8.

3 16.3.5. By inviting and disseminating this and other manufacturer-
4 sponsored CE material, Walgreens caused its pharmacists to be misinformed about the
5 risks of addiction, with the result that they would be more willing to fill opioid
6 prescriptions, less likely to ask important questions, and less able to fulfill their
7 responsibilities to investigate red flags to prevent illegitimate use and diversion. Lembke
8 Decl. ¶ 119.

9 16.3.6. Similarly, in 2014, Walgreens developed a tool that would help field
10 leaders identify pharmacists who were “not dispensing a lot of controlled drugs.” P-
11 19607_00001 to 00002. The head of Walgreens’ Pharmaceutical Integrity group, Tasha
12 Polster, recommended that field leaders “encourage the pharmacist[s] to [] obtain more
13 information on pain management such as [CE] courses in order to better understand
14 treatment protocol and feel more comfortable in filling controlled substances.” P-
15 19607_00001 to 00002.

16 **3. Evidence of Lack of Due Diligence by Walgreens**

17 16.4. The evidence shows that it is more likely than not that Walgreens
18 pharmacists failed to perform due diligence on significant numbers of prescriptions with
19 red-flags of diversion and dispensed those prescriptions without investigating or clearing
20 the red flags.

21 16.4.1. The People’s expert, Elizabeth Park, reviewed Walgreens’
22 prescription records and determined that, from 2006 to 2020, Walgreens pharmacists in
23 San Francisco performed and documented the due diligence reasonably necessary to
24 resolve red flags presented by the prescription for fewer than 5 percent of prescriptions
25 with such flags. Park Decl. ¶ 24.

26 16.4.1.1. Dr. Park conducted a thorough analysis of Walgreens’ due
27 diligence records for a little under 2,300 (2,265, to be precise) opioid and opioid cocktail
28 prescriptions that were dispensed by Walgreens pharmacies in San Francisco from 2010 to

2019 and which triggered one or more red flags. *See* Park Trial Tr. 963:6–964:24. Dr. Park reviewed all materials associated with these prescriptions—including each data field associated with electronic prescription records for these prescriptions, as well as any attached TDGFD checklists or copies of the original prescriptions, in an effort to locate due diligence records wherever they could be found. *See* Park Trial Tr. 977:3–20; Park Decl. ¶ 19.

16.4.1.2. Walgreens’ written dispensing policies required Walgreens’ pharmacists to document their diligence in clearing red-flagged prescriptions. *See* para. 15.8.4, *supra*.

16.4.1.3. It is a basic tenet of pharmacy practice that, “if you didn’t document it, it didn’t happen.” Gayle Dep. 51:21–52:5; *see also* para. 15.8.3, *supra*.

16.4.1.4. Although it is possible that in some instances, Walgreens’ pharmacists may have performed due diligence and failed to document it, in light of Walgreens’ policy requiring documentation and in light of the prevailing professional standard requiring documentation, the Court concludes that in the vast majority of cases where there is no record of due diligence, the pharmacist did not clear the red flag.

16.4.2. Walgreens’ electronic dispensing records on their face reveal on absence of documented due diligence. The two fields specifically relevant to red flag due diligence, the “annotations” field and the “patient comments” field, *see* Polster Trial Tr. 2415:1–4, were simply left blank for all but 240 and 319 prescriptions, respectively, of the nearly 2,300 reviewed. Of the latter number, 266 of the 319 fields contained only e-mail addresses. *See* Park Trial Tr. 973:4–976:17.

16.4.3. A 2015 Walgreens audit of its stores found that fewer than 60 percent were complying with Walgreens’ post-2013 “Target Drug Good Faith Dispensing” checklist requirement. P-15085_00007.

16.4.4. Around 2010, Walgreens pharmacists reported to a manager at Walgreens’ Jupiter, Florida, distribution center that it was “not their job” to meaningfully

1 investigate prescriptions; if “[t]hey ha[d] a script, they w[ould] fill it.” Lucas Fla.
 2 Test. 632:2–6.

3 16.4.5. “Target Drug Good Faith Dispensing” checklists were completed
 4 equally rarely—or even more rarely—by Walgreens pharmacies in San Francisco,
 5 according to documents produced by Walgreens in this litigation. Catizone Decl. ¶¶ 51–
 6 52; P-29849. If additional productions would have cast Walgreens in a more favorable
 7 light, Walgreens presumably would have made them.

8 16.4.6. Given that Walgreens dispensed 1.4 million red-flagged opioid
 9 prescriptions in San Francisco, *see* para. 17.1.5, *infra*, and given that Walgreens’ diligence
 10 records suggest that due diligence was performed for only approximately five percent of
 11 those prescriptions, it is reasonable to conclude that Walgreens dispensed more than 1.3
 12 million opioid prescriptions with red flags of diversion that were not cleared before the
 13 drugs were dispensed. The Court further concludes that even if Walgreens’ pharmacists
 14 performed some due diligence that they did not document, it is more likely than not that
 15 Walgreens dispensed a significant number of prescriptions with red flags of diversion that
 16 were not cleared before the drugs were dispensed.

17 16.4.7. The conclusion that Walgreens failed to perform due diligence on
 18 red-flagged prescriptions for which there is no documentation of investigation is
 19 supported by other evidence. Walgreens partnered with opioid manufacturers like Purdue
 20 to “educate” its pharmacists in an effort to overcome their hesitation to dispense addictive
 21 narcotics. For many years, Walgreens’ written dispensing policies provided little guidance
 22 and directed pharmacists to dispense opioid prescriptions if the doctor “said it was okay.”
 23 That policy changed after a series of DEA interventions, but the policy that followed had
 24 fundamental flaws, including the fact that it did not cover the most commonly abused
 25 prescription opioids. Walgreens pharmacies were extremely understaffed, leaving its
 26 pharmacists with insufficient time to conduct adequate due diligence on opioid
 27 prescriptions. The overwhelming priority for Walgreens pharmacists was to fill as many
 28 prescriptions as possible, as quickly as possible. Walgreens withheld critical data about

1 potentially suspicious prescribers from these pharmacists and failed to implement
 2 effective methods for pharmacists to communicate their concerns about potentially
 3 illegitimate prescriptions and prescribers. *See* paras. 16.1–16.3, *supra*. Taken together,
 4 this evidence supports the inference that Walgreens regularly dispensed red-flagged
 5 opioid prescriptions without sufficient due diligence.

6 **V. Causation in Fact**

7 **17.** Walgreens’ conduct has been a cause in fact of the public nuisance in San
 8 Francisco. Walgreens has been a substantial factor in causing the opioid epidemic in San
 9 Francisco. The opioid epidemic would not have occurred to its present extent without
 10 Walgreens’ conduct.

11 **A. The Connection Between Walgreens’ Conduct and Diversion in San Francisco**

12 17.1. Diversion of prescription opioids in San Francisco would not have reached
 13 its full extent without Walgreens’ conduct.

14 17.1.1. Diversion occurs when prescription opioids are used for other than
 15 legitimate medical purposes, that is when they are used non-medically. Opioids that are
 16 dispensed without a prescription issued for a legitimate medical purpose by a practitioner
 17 acting in the usual course of his professional practice are, by definition, diverted, because
 18 they cannot be used medically—that is, they cannot be taken as directed by a physician for
 19 a medical purpose. *Cf.* para. 5.2.2.4, *supra*.

20 17.1.2. It is more likely than not that Walgreens’ failure to maintain
 21 effective controls against diversion led to the dispensing of prescriptions that were not
 22 issued for a legitimate medical purpose and thus were diverted. Multiple circumstances
 23 and multiple types of evidence lead inexorably to this conclusion.

24 **1. Volume of Red-Flagged Prescriptions Dispensed Without Due Diligence**

25 17.1.3. From January 2006 to June 2020, Walgreens pharmacies in San
 26 Francisco dispensed 2.47 million opioid prescriptions, equaling 155.8 million dosage units
 27 of opioids. McCann Decl. ¶¶ 22, 57. The number of dosage units dispensed by Walgreens
 28 increased each year from 2006 through 2011. McCann Decl. ¶ 57; McCann Trial Tr. 1192.

1 17.1.4. The People’s expert Carmen Catizone identified 14 red flags of
 2 diversion based on the categories described above. *See* para. 15.6.2, *supra*. The People’s
 3 expert Dr. Craig McCann applied these 14 red flags to Walgreens’ prescription records to
 4 determine the number of opioid and opioid cocktails prescriptions dispensed by
 5 Walgreens that triggered one or more of the flags.

6 17.1.4.1. For the purposes of quantitative analysis, the People’s expert
 7 Dr. Craig McCann reasonably and reliably operationalized the dispensing red flags
 8 identified by the People’s experts Carmen Catizone and Dr. Elizabeth Park. While red flag
 9 due diligence necessarily involves exercise of a pharmacist’s professional judgment, the
 10 algorithmic red flag definitions developed by Dr. McCann with Mr. Catizone’s assistance
 11 capture real-world indicia of diversion such that reliable conclusions may be drawn from
 12 Dr. McCann’s aggregate analysis.

13 17.1.4.2. As to the “long distance travel” flag specifically, 25 miles is a
 14 reasonable approximation of a distance that should raise a pharmacist’s suspicions in the
 15 dense urban environment of San Francisco and the Bay Area.

16 17.1.4.3. Walgreens argues that the red flags the People identified and
 17 analyzed are over-inclusive and do not reflect standards in the practice of pharmacy. The
 18 People’s evidence shows, however, that Walgreens’ own GFD policy recognized the same
 19 categories of red flags—long distances travelled, doctor shopping, pharmacy shopping,
 20 drug cocktails, excessive dispensing, pattern prescribing, early refills, and cash payments.
 21 These categories are also recognized by NABP and other stakeholders. *See* para. 15.6.2,
 22 *supra*. The Court finds that the flags identified by Mr. Catizone are appropriate indicators
 23 of diversion and reflect professional standards and consensus.

24 17.1.4.4. Walgreens argues that the People’s flagging method is over-
 25 inclusive because it flags prescriptions that only become suspicious in combination with
 26 other prescriptions. But adjusting the flagging methodology to account for this criticism
 27 would not materially change the results. The adjusted method would flag 55.4 percent of
 28 the prescriptions for opioids and opioid cocktail drugs that Walgreens dispensed, instead

1 of the 61.5 percent of such prescriptions flagged by the original approach. McCann
 2 Rebuttal Decl. ¶¶ 4–5.

3 17.1.5. Of the approximately 2.5 million opioid prescriptions dispensed by
 4 San Francisco Walgreens pharmacies, 1.4 million or 57.6 percent were flagged by at least
 5 one of 14 red flags. McCann Trial Tr. 1181:7–10. (Although this number does not take
 6 account of the adjustment discussed above, given the modest nature of the reduction
 7 resulting from that adjustment, the Court does not believe that applying the adjustment
 8 would materially alter any of its conclusions.) Nearly one third (32.13 percent) of the 1.4
 9 million flagged opioid prescriptions had more than one red flag. Catizone Decl. ¶ 70;
 10 McCann Decl. ¶ 60; McCann Trial Tr. 1181:24. Of the approximately 2.9 million opioid
 11 and opioid cocktail prescriptions dispensed by San Francisco Walgreens pharmacies, 61.5
 12 percent had at least one red flag. McCann Decl. ¶ 22. *See generally* P-04744 (McCann
 13 “Summary of Dispensing Red Flag Analysis”).

14 17.1.6. It is more likely than not that Walgreens dispensed the vast majority
 15 of these red-flagged prescriptions without anyone performing the requisite due diligence.
 16 *See* para. 16.4, *supra*.

17 17.1.7. Given the expected danger of diversion, and the fact that red-flags
 18 are designed to identify circumstances indicative of diversion, it is more likely than not
 19 that because Walgreens dispensed a significant number of red-flagged prescriptions
 20 without due diligence to clear the suspicions, a substantial number of such prescriptions
 21 were in fact diverted. Catizone Decl. ¶¶ 71, 86, 95. Given the likelihood that Walgreens
 22 dispensed a significant number of opioid prescriptions with red flags of diversion that
 23 were not cleared, the Court finds that it is more likely than not that a significant number of
 24 the opioids dispensed pursuant to those prescriptions were not for a legitimate medical
 25 purpose and thus were diverted.

26 17.1.7.1. Walgreens argues that the inference of diversion is faulty
 27 because, (a) according to Walgreens, 99.5 percent of doctors do not write illegitimate
 28 prescriptions; and (b) significant percentages of prescriptions written by many doctors

1 who are above reproach, including doctors employed by the City and its agencies,
2 triggered one or more red flags. The Court rejects this view of the evidence.

3 17.1.7.1.1. The evidence does not support Walgreens’
4 assertion that 99.5 percent of doctors prescribe appropriately. There is no evidence in the
5 record to quantify the number of doctors who prescribe illegally. Walgreens cites to the
6 testimony of former head of DEA’s Office of Diversion Control Joe Rannazzisi, but Mr.
7 Rannazzisi explained that his statement (“99 percent or more of prescribers were not
8 overprescribing”) was “made in the context of how many people were actually charged
9 with administrative criminal and civil violations.” Rannazzisi Dep. 1781:15–20. The
10 Court recognizes that Mr. Rannazzisi was speaking extemporaneously and without
11 reference to statistical evidence of the actual number or percentage of doctors who
12 prescribe illegally; the number of prescribers who prescribe illegally but have not been
13 prosecuted or disciplined is unknown. In any event, the relevant factor is not how many
14 doctors wrote illegitimate prescriptions, but rather how many prescriptions—and how
15 many MMEs—those doctors accounted for. A small number of doctors can and do
16 account for a disproportionate number of illegitimate prescriptions. *Cf.* para. 17.1.11,
17 *infra*.

18 17.1.7.1.2. That even doctors who are above reproach may
19 write large numbers of red-flagged prescriptions does not undermine the inference that
20 Walgreens dispensed illegitimate prescriptions. The fact that many red flags will, if
21 investigated, be cleared does not mean that they all will be. Nor will the diverted
22 prescriptions be distributed evenly among all prescribers, as Walgreens has suggested. It
23 is not only possible, but even likely, that most, if not all, of the red-flagged prescriptions
24 written by one particular doctor would be cleared by investigation, while virtually none
25 written by other doctors would be. Dr. Claire Horton, for example, and other physicians
26 working in San Francisco’s safety-net network, practice “in a really high-risk setting with
27 really high-risk patients.” It is therefore not inappropriate that a high percentage of their
28 prescriptions would trigger but ultimately clear a pharmacist’s review. Horton

1 Dep. 48:21–49:16, 149:19–150:21, 159:22–160:16, 170:19–171:16. The same cannot be
 2 said, for example, of physicians who sell opioid prescriptions without examination. *See*
 3 para. 17.1.11, *infra*. Moreover, even a doctor above reproach may unwittingly write an
 4 illegitimate prescription to a doctor-shopping patient who is deceiving them and is seeking
 5 opioids for non-medical use. The statistical inference remains that, if you fill enough red-
 6 flag prescriptions without due diligence, many of them will be diverted. It is not necessary
 7 to know which ones and not reasonable to infer that they will be distributed evenly among
 8 the prescribers whose prescriptions were flagged.`

9 17.1.8. The sheer volume of red-flagged prescriptions dispensed without
 10 due diligence is not the only circumstance supporting the inference that Walgreens' failure
 11 to provide effective controls against diversion led to the dispensing of prescriptions that
 12 were not for medical use and were instead diverted. Each of these circumstances, alone
 13 and in combination, supports that inference.

14 **2. Distribution and Receipt of Suspicious Orders**

15 17.1.9. The inference that Walgreens dispensed illegitimate prescriptions
 16 from its stores is supported by the fact that Walgreens shipped large volumes of
 17 suspicious orders to its stores, which in turn dispensed many red-flagged prescriptions.

18 17.1.9.1. From 2006 to 2014, Walgreens distributed 102.4 million
 19 dosage units of opioids to Walgreens pharmacies in San Francisco. McCann Decl. ¶ 10.

20 17.1.9.2. The People's expert Dr. Craig McCann applied seven
 21 algorithms that could have been used to identify suspicious orders. The results showed
 22 that the percentage of dosage units (pills, patches, etc.) distributed by Walgreens to its
 23 pharmacies that would have been flagged as suspicious under at least one of the
 24 algorithms ranges from 4.3 to 67.4 percent, or from 4 million to 63.2 million dosage units.
 25 McCann Decl. ¶ 16.

26 17.1.9.2.1. There is no evidence in the record to suggest that
 27 the seven distribution algorithms do not represent appropriate methodologies for
 28 identifying suspicious orders. Several of the methods are similar to those used by

Walgreens itself, or by other distributors which distributed to it. *Compare* McCann Decl. ¶ 49 (describing “three times trailing twelve-month average” method), *with* McCann Trial Tr. 1171:22–1172:8 (Walgreens reporting “orders for the month ... exceed[ing] three times the monthly average over the prior six months.”); *see also* McCann Decl. ¶ 50 (applying dosage unit threshold taken from policies of McKesson Corp., which distributed prescription opioids to Walgreens, *see* P-29835_00012), ¶ 51 (applying dosage unit threshold taken from policies of Cardinal Health, which distributed prescription opioids to Walgreens, *see* P-29835_00012).

17.1.9.3. Throughout the period during which Walgreens distributed opioids to its stores, it had no effective SOM system in place. *See* para. 14, *supra*.

17.1.9.4. Given the large number of suspicious orders of opioids shipped to Walgreens stores without due diligence, it is more likely than not that a significant number of those opioids were dispensed illegitimately and thus diverted.

17.1.10. The inference that Walgreens dispensed illegitimate prescriptions from its stores is further supported by the fact that *all* of the distributors that shipped to Walgreens shipped large volumes of suspicious orders to Walgreens’ stores, which in turn dispensed many red-flagged prescriptions.

17.1.10.1. From 2006 to 2014, the Walgreens pharmacies in San Francisco received 126.9 million dosage units (pills, patches, etc.) from distributors Walgreens, AmerisourceBergen, Cardinal Health, and McKesson Corporation. McCann Decl. ¶ 12; P-29835_00012. These 126.9 million pills (or patches, etc.) represent 58.7 percent of the prescription opioids shipped to retail and chain pharmacy dispensers in San Francisco. McCann Decl. ¶ 39; P-29835_00002. When Dr. McCann applied the same seven algorithms discussed above to these shipments, the results showed that the percentage of dosage units distributed by all of the distributors that shipped opioids to Walgreens pharmacies in San Francisco that would have been flagged as suspicious under at least one of the algorithms ranges from 4.1 to 64.4 percent. McCann Decl. ¶ 14; *see also* CT4-MCCANN-DEMO-00024_00020.

17.1.10.2. The shipment of so many suspicious orders to Walgreens stores is a further circumstance suggestive of diversion at those stores.

3. Dispensing “Bad Doctors” Prescriptions

17.1.11. The inference that Walgreens dispensed illegitimate prescriptions from its stores as a result of its failures to maintain effective controls against diversion is further supported by the fact that Walgreens filled tens of thousands of opioids prescriptions written by 31 highly suspicious prescribers who ultimately lost their medical licenses; some were criminally prosecuted. Several of these prescribers had been identified in Walgreens’ own dispensing data analyses (of which it purposely kept its pharmacists ignorant) as suspicious outliers. Several were known to Walgreens’ pharmacists to be dangerous, even too dangerous, to dispense for—but these pharmacists had no way to communicate their concerns broadly, and they were ignored. Walgreens continued dispensing for these prescribers in some cases weeks or *months* after their licenses had been surrendered or revoked.

17.1.11.1. The People identified 31 prescribers in San Francisco and the Bay Area who were disciplined for prescription opioid misconduct. *See* P-18323a. Together, these 31 prescribers accounted for 7.8 percent of all opioid MMEs dispensed at San Francisco Walgreens stores from 2006 to 2020. In 2010, they accounted for 16.7 percent of all MMEs dispensed at San Francisco Walgreens stores. Walgreens dispensed more than 6 million dosage units written by these 31 prescribers in San Francisco; for the Bay Area, it was more than 20 million dosage units. *See* P-18323a; P-28506b. *Compare* para. 17.1.3 (total of 155.8 million dosage units dispensed), *supra*.

17.1.11.2. Dr. Guido Gores was the second highest opioid prescriber in San Francisco and in the top 1 percent nationwide. *See* Keller Decl. ¶¶ 18–20. In February 2021, Dr. Gores surrendered his license in response to allegations that he prescribed opioids to patients before examining them; prescribed opioids with Adderrall, resulting in a patient’s death by “acute mixed drug intoxication”; and committed other acts of gross negligence. Catizone Decl. ¶ 73; P-22297_00011 to 00022. Between 2006 and 2020,

1 Walgreens filled nearly 10,000 opioid prescriptions from Dr. Gores, of which
 2 approximately 82 percent triggered at least one red flag. Catizone Decl. ¶ 74; *see* P-
 3 28506b. One of his prescriptions hit 10 out of the 14 red flags, yet was still dispensed by
 4 Walgreens in 2018. Catizone Decl. ¶ 77.

5 17.1.11.2.1. The absence of a system for identifying “bad
 6 doctors” led Walgreens to continue filling prescriptions written by Dr. Gores well after
 7 they should have stopped. As early as 2012, Dr. Gores stood out in Walgreens’ dispensing
 8 data as an outlier high-volume prescriber. *See* P-27369a (nine entries for Gores on
 9 prescriber risk index). Walgreens withheld that data from its pharmacists, *see* para. 16.2.9,
 10 *supra*, but even without it, by 2019 two separate Walgreens pharmacies (at 1301 Market
 11 Street and 1300 Bush Street) had of their own initiative stopped filling Dr. Gores’s
 12 controlled substance prescriptions. P-27265 (citing high opioid prescription volume from
 13 general practitioner as cause for concern); P-27532_00003. But because Walgreens lacked
 14 a method to escalate such concerns systematically, other San Francisco Walgreens
 15 pharmacies kept filling Dr. Gores’s prescriptions. Catizone Decl. ¶ 75. After district
 16 manager Ronda Lowe would have reviewed the refusal to fill Dr. Gores’s prescriptions
 17 implemented by the 1301 Market Street pharmacy, *see* Lowe Trial Tr. at 3048:15–25,
 18 3049:20–50:1; 3051:11–17; P-27532, San Francisco Walgreens dispensed an additional
 19 86,904 opioid dosage units on Dr. Gores’s prescriptions. P-28518_GORES_EXCERPT;
 20 *see* P-28506b.

21 17.1.11.2.2. Later in 2019, other Walgreens pharmacists
 22 expressed similar concerns to higher levels of Walgreens leadership. P-27532_00003 to
 23 00004. Walgreens’ Pharmaceutical Integrity department was also made aware that Dr.
 24 Gores was also being investigated by the DEA by no later than September 2019. P-
 25 27531_00002 to 00003. Again Walgreens leadership did not share this information, and
 26 nearly all of its San Francisco pharmacies continued to fill Dr. Gores’ prolific opioid
 27 prescriptions for the remainder of 2019 and into 2020. Catizone Decl. ¶ 76; *see* P-28506b.
 28

17.1.11.3. Dr. Andrew Giovannini was a high-volume prescriber, ranking 16th in the nation by MME in 2010. *See* Keller Decl. ¶ 12–17. In that year, 13 percent of all MMEs dispensed by Walgreens pharmacies in San Francisco were dispensed on Dr. Giovannini’s prescriptions. *See* P-28506b. In May 2012, Dr. Giovannini surrendered his medical license for routinely prescribing dangerously high levels of opioids without appropriate examination or documentation. Catizone Decl. ¶ 78; P-27514. In just five years from 2006 to 2010, San Francisco Walgreens pharmacies filled more than 9,000 of Dr. Giovannini’s opioid prescriptions. Despite the fact that Dr. Giovannini had been practicing internal medicine since 1965, the volume of his opioid prescriptions increased thirteen-fold from 2006 to 2010. Catizone Decl. ¶ 79; *see* P-28506b. Ninety-four percent of those opioid prescriptions triggered one or more red flags. *See* P-28506b. Twelve oxycodone prescriptions written by Dr. Giovannini and filled at various Walgreens stores in San Francisco—3398 Mission Street, 1189 Potrero Avenue, and 4129 18th Street—hit at least 9 out of the 14 red flags. Catizone Decl. ¶ 80; *see* P-28506b.

17.1.11.3.1. Walgreens pharmacists were aware that Dr. Giovannini’s prescribing practices were suspicious and suggestive of diversion. *See* Gayle Dep. 69:15–71:4, 96:15–97:19, 102:10–102:23; Lo Decl. ¶ 22. But because Walgreens lacked a method to escalate such concerns systematically, other San Francisco Walgreens pharmacies kept filling Dr. Giovannini’s prescriptions.

17.1.11.4. Dr. Collin Leong had thousands of his opioid prescriptions filled at Walgreens before he surrendered his license in 2014 (and ultimately pleaded guilty to felony charges) for selling opioid prescriptions to patients without examination or medical justification. Catizone Decl. ¶ 82; P-27610 (license proceedings); P-27568 (criminal proceedings); *see* P-28506b. Between 2006 and 2013, Walgreens’ pharmacies in the Bay Area filled almost 2,200 of Dr. Leong’s opioid prescriptions, with almost 79 percent triggering red flags. *See* P-28506b.

17.1.11.4.1. As early as 2012, Dr. Leong stood out in Walgreens’ dispensing data as an outlier high-volume prescriber. *See* P-27369a (eight

1 entries for Leong on prescriber risk index). Even without this data (which Walgreens
 2 pharmacists did not have access to, *see* para. 16.2.9, *supra*), by early 2013, “a lot of
 3 [Walgreens] stores had tagged [Dr. Leong’s] name as do not fill for control[led
 4 substances].” P-27533_00001. Walgreens Pharmacist Rebecca Gayle found Dr. Leong’s
 5 prescriptions particularly suspicious and tried to warn other pharmacists in her area about
 6 him. Gayle Dep. 69:15–72:1, 100:24–102:21. But because Walgreens lacked a method to
 7 escalate such concerns systematically, other San Francisco Walgreens pharmacies kept
 8 filling Dr. Leong’s prescriptions. Catizone Decl. ¶ 83; *see* P-28506b.

9 17.1.11.5. Dr. John Pierce was a high-volume opioid prescriber. From
 10 1997 to 2017, “Pierce wrote the fifth highest volume of opioid prescriptions and the sixth
 11 highest volume of dosage units in San Francisco.” Keller Decl. ¶ 25; *see* Keller Decl.
 12 ¶¶ 25–28. Dr. Pierce surrendered his license in response to allegations he prescribed
 13 opioids without examination or documentation. P-28430_00017, 00033. Of the more than
 14 10,000 of his opioid prescriptions that Walgreens dispensed in the Bay Area, 75 percent
 15 triggered at least one red flag. Catizone Decl. ¶ 84; *see* P-28506b.

16 17.1.11.5.1. Walgreens pharmacist Rebecca Gayle noticed
 17 Pierce’s suspicious prescribing around 2016. Gayle Dep. 75:16–76:12, 79:6–17. By
 18 August 17, 2019, Walgreens knew that Dr. Pierce had been placed on a California State
 19 Board of Pharmacy list of “prescribers whose authority to prescribe controlled substances
 20 has been restricted by the Medical Board of California.” P-28997 _ 00002 (e-mail to
 21 Ronda Lowe among others); *see* Lowe Trial Tr. 3064:1–24. Dr. Pierce surrendered his
 22 license on December 31, 2019. P-28430_00001. Nonetheless, Walgreens continued filling
 23 his prescriptions *for months*, until April 16, 2020. Catizone Decl. ¶ 84; *see* P-28506b.

24 17.1.11.6. Dr. Ray Seet was a high-volume opioid prescriber. *See* P-
 25 27369a (nine entries for Seet on Walgreens’ prescriber risk index). Ninety-eight percent
 26 of Dr. Seet’s nearly 900 opioid prescriptions filled at San Francisco Walgreens stores
 27 triggered at least one red flag. Catizone Decl. ¶ 85; *see* P-28506b. Dr. Seet lost his license
 28 in 2013 on charges among others of prescribing opioids without examination. *See* P-

1 27609. Nevertheless, Walgreens continued to dispense his prescriptions for another
 2 month. Catizone Decl. ¶ 85; P-28506b.

3 17.1.11.7. Given that these five doctors, and the other 26 identified by
 4 the People, were engaged in sufficient illegitimate prescribing to result in discipline or
 5 criminal prosecution, the Court infers that many or most of the opioid prescriptions
 6 written by these doctors were illegitimate and thus diverted.

7 17.1.11.8. It does not matter that these doctors may have written some
 8 legitimate opioid prescriptions in the course of their careers. The fact that they wrote
 9 sufficient numbers of illegitimate prescriptions to result in the loss or suspension of their
 10 licenses and sometimes in criminal prosecution supports the inference that substantial
 11 numbers of the prescriptions they wrote for opioids were not legitimate.

12 17.1.11.9. Nor does it matter that some of these doctors' patients may
 13 have had legitimate pain conditions for which some legitimate opioid prescription could
 14 have been written. The prescriptions the patients received from these doctors did not
 15 reflect or comport with medical use of the drugs and the resulting non-medical use of the
 16 drugs carried the risks associated with non-medical use, regardless of whether, under other
 17 circumstances, the same patients might have used prescription opioids medically.

18 **4. Other Evidence Supporting the Inference of Diversion**

19 17.1.12. There are other reasons to believe that Walgreens' failures to
 20 maintain effective controls resulted in the dispensing of illegitimate prescriptions. When
 21 Walgreens performed a trial in 2012 of the then-new TDGFD checklists, dispensing of
 22 target drugs dropped by as much as 38 percent. P-20639_00011. *See also* P-20639_00011
 23 ("Realistically, bottom line, yes sales are going to be impacted. However, some would say
 24 that we shouldn't even be filling some of these prescriptions."). The fact that Walgreens
 25 pharmacists were unable to dispense so many prescriptions under a more robust system of
 26 due diligence supports the inference that Walgreens' failure to implement such a system
 27 resulted in the dispensing of illegitimate prescription.
 28

17.1.13. In 2009, the DEA charged one Walgreens pharmacy in San Diego with dispensing controlled substances on prescriptions written by unlicensed prescribers, on prescriptions written by prescribers on-line, and to people Walgreens knew or should have known were diverting the drugs. P-00015_00019.

17.1.14. Walgreens pharmacists admit they filled opioid prescriptions in San Francisco that were likely diverted. At one Walgreens pharmacy on King Street, prescription opioids were being openly sold in the pharmacy parking lot moments after being dispensed by Walgreens pharmacists. Gerspacher Dep. 82:1–82:8; *see also* Gerspacher Dep. 33:17–34:1 (pharmacist realized “I shouldn’t have” filled a prescription presented under suspicious circumstances); Lo Trial Tr. 919:22–24 (“I know that I” filled prescriptions that should not have been filled.); Gayle Dep 165:9–19 (“I’m sure I let diverted medications go through.”). Although this evidence is anecdotal and necessarily relates to a small number of prescriptions, in combination with the rest of the evidence, it provides additional support for the inference that Walgreens in fact dispensed illegitimate prescriptions. Indeed, based on the testimony of Jeremy Gerspacher, the Court specifically rejects Walgreens’ argument that the People have failed to identify any particular instances of diversion.

17.1.15. The Court considers, as well, that the entire premise of and rationale for the obligation to maintain effective controls against diversion is that diversion results in the absence of effective controls. *See* para. 5.2.2, *supra*. This rationale, too, supports the inference that the failure to maintain effective controls against diversion more likely than not resulted in diversion.

17.1.16. It is more likely than not that the quantity of opioids diverted from prescriptions dispensed by Walgreens was significant.

17.1.16.1. First, in absolute terms, Walgreens dispensed approximately 1.4 million red-flagged opioid prescriptions in San Francisco (which would be subject to only a modest reduction, were the Court to account for Walgreens’ over-flagging criticism). *See* para. 17.1.5, *supra*. The Court has already found that it is more likely than

1 not that large numbers of these prescriptions were diverted. *See* paras. 17.1.7–17.1.10,
2 *supra*.

3 17.1.16.2. Second, the percentage of MMEs dispensed pursuant to
4 prescriptions written by doctors who were disciplined or criminally prosecuted further
5 demonstrates that the quantities of diverted prescriptions were likely large. *See* para.
6 17.1.11, *supra*.

7 17.1.16.3. Third, Walgreens maintains a significant market share of
8 dispensing in San Francisco, such that the prescriptions it dispenses represent a significant
9 portion of the total. The People’s expert Dr. McCann determined that, based on the
10 ARCOS data received from the DEA, Walgreens has a 58.7 percent share of the retail and
11 chain pharmacy market. *See* para. 17.1.10.1, *supra*.

12 17.1.16.3.1. The Court rejects Walgreens’ argument that the
13 correct denominator for calculating its market share includes hospitals and opioid
14 treatment programs. There is no evidence, and no reason to believe, that such facilities are
15 important sources of opioid diversion, and such facilities are materially differently
16 situated with respect to the risks of diversion. Unlike Walgreens, for the most part
17 treatment facilities do not appear to dispense bottles of pills to patients, and among other
18 restrictions may only dispense “take-home doses” in limited circumstances. *See* 42 C.F.R.
19 § 8.12(h)(3)(i), (h)(4)(i), (h)(4)(i)(2), (f)(5)(i). Inpatient hospital pharmacies, like ZSFG
20 inpatient pharmacies, “provide medications to patients for direct administration under
21 medical supervision.” Patel Decl. ¶ 3. Regardless, even were the Court to accept
22 Walgreens’ claim of a 27 percent share of this expanded denominator, a 27 percent market
23 share is more than sufficient to support the findings made here.

24 17.1.16.4. Walgreens challenges the inference that it dispensed a
25 significant quantity of diverted opioids by pointing to evidence that not all diverted
26 opioids originate with an illegitimate prescription. This may be true, but it is beside the
27 point and in no way undermines the inference that Walgreens dispensed illegitimate
28 prescriptions.

1 17.1.16.4.1. Although all opioids dispensed pursuant to an
2 illegitimate prescription are diverted, the converse is not necessarily true: not all diverted
3 opioids must originate with an illegitimate prescription. But the evidence described above
4 makes it more likely than not that Walgreens dispensed substantial quantities of
5 *illegitimate* prescriptions. The People have demonstrated, in absolute numbers, the likely
6 scale of diverted opioids Walgreens dispensed. The possibility that *other* opioids,
7 originally dispensed pursuant to legitimate prescriptions, were later diverted—a type of
8 diversion sometimes referred to as “medicine cabinet diversion”—does not affect the
9 volume of opioids that Walgreens likely dispensed pursuant to illegitimate prescriptions.

10 17.1.16.4.2. To the extent that Walgreens means to suggest
11 that all or nearly all diverted opioids in San Francisco were originally dispensed pursuant
12 to a legitimate prescription, rather than pursuant to the illegitimate prescriptions
13 Walgreens dispensed, the Court rejects that argument.

14 17.1.16.4.3. Walgreens points to information presented by the
15 People’s expert, Dr. Keyes, to support its contention that “most” diversion originates in
16 legitimate prescriptions. This information does not support Walgreens’ conclusion. Dr.
17 Keyes cited a study that found that 50.5 percent of people get the pills they misuse free
18 from friends or relatives. Keyes Decl. ¶ 82. But the fact that users obtained pills free from
19 friends or relatives tells us nothing about how those friends or relatives originally obtained
20 the drugs. The friends or relative may have obtained the opioids through an illegitimate
21 prescription and later shared them for free. The data referred to by Dr. Keyes provides
22 information about where people get the drugs they misuse, not about how those drugs
23 originally came to be dispensed, whether legitimately or illegitimately.

24 17.1.16.4.4. Even if Walgreens were correct about what Dr.
25 Keyes data shows, that would mean that 49.5 percent of diverted drugs were originally
26 dispensed through illegitimate prescriptions, which still represents a substantial and
27 significant percentage of diverted opioids.

28

1 17.1.16.4.5. Dr. Keyes herself testified that diversion of
 2 opioids obtained from doctor-shopping and pill mills, both sources of illegitimate
 3 prescriptions, are substantial contributing factors to the opioid epidemic. *See* Keyes Trial
 4 Tr. 2232:9–17.

5 17.1.16.4.6. The Court credits the testimony of the former
 6 head of DEA’s Office of Diversion Control Joe Rannazzisi, who does not believe that so-
 7 called “medicine cabinet” diversion is the most common form of diversion and that such a
 8 conclusion would be implausible “given the huge volume” of “illegitimate and illegal
 9 prescriptions” leaving pharmacies. Rannazzisi Dep. 1808:22–1810:22. In light of Mr.
 10 Rannazzisi’s former position, the Court credits his conclusion that illegitimate
 11 prescriptions represent a significant portion of diverted prescriptions.

12 17.1.17. The Court rejects Walgreens’ argument that it cannot have
 13 contributed to the opioid epidemic because, if it had, the DPH would not contract with it
 14 for its 340B drug pricing program.

15 17.1.17.1. Section 340B of the federal Public Health Service Act
 16 requires pharmaceutical manufacturers to offer drugs at a discount to participating public
 17 safety-net health systems. *See* 42 U.S.C. § 256b. DPH administers its 340B program
 18 through Walgreens, which met the request-for-proposal criteria, Patel Trial Tr. 1319:24–
 19 1320:1, and has the widest geographical coverage in San Francisco. That DPH recognizes
 20 Walgreens’ ability to provide appropriate drug discounts in no way demonstrates that
 21 Walgreens has not also contributed to the opioid epidemic by failing to provide effective
 22 controls against diversion.

23 17.1.17.2. Nor is Walgreens’ suggestion that DPH’s right to conduct
 24 audits under the 340B program somehow clears Walgreens of responsibility. It is true that
 25 DPH’s contract with Walgreens authorizes DPH to audit Walgreens’ 340B records
 26 annually to ensure that “non-Eligible Patients” have not received discounts. WAG-MDL-
 27 02961.00011. The nature of the data DPH receives undermines Walgreens’ suggestion
 28 that DPH could use this audit to evaluate Walgreens’ opioid dispensing practices. Opioids

1 make up only approximately one percent of 340B prescriptions, and the data DPH
2 receives regarding these prescriptions does not contain any of the relevant fields necessary
3 to conduct any sort of due diligence analysis. See Patel Trial Tr. 1342:7–1345:16.

4 **B. The Connection Between Diversion in San Francisco and the Opioid Epidemic**

5 17.2. The opioid epidemic would not have reached its present extent without
6 diversion of prescription opioids in San Francisco.

7 17.2.1. Diverted prescription opioids are themselves directly harmful to
8 public health.

9 17.2.1.1. The Court accepts the judgment of Walgreens itself, which
10 has internally acknowledged that prescription opioid “misuse”—that is, diversion—
11 imposes substantial burdens on the public. *See* P-25546_00008 (estimating nationwide
12 costs of prescription opioid misuse to be more than \$55 billion).

13 17.2.1.2. Prescription opioids are controlled substances whose
14 circulation is restricted by law and policy to the closed system of distribution precisely
15 because of their extraordinary capacity to cause harm when used outside that system. *See*
16 para. 5.2.2, *supra*.

17 17.2.1.3. “One of the biggest risk factors for addiction generally is
18 simple access to addictive drugs. When supply of an addictive drug is increased, more
19 people become addicted to and suffer the harms of that drug.” Lembke Decl. part II.A; *see*
20 Lembke Decl. ¶¶ 4, 163.

21 17.2.1.3.1. The consensus in the scientific literature, which
22 the Court accepts, is that the role of supply, rather than economic factors, is the principal
23 causal factor driving increases in opioid-related harm, including OUD. Keyes Decl.
24 ¶¶ 75–76, 78–79, 89, 127, 133; *see especially* Keyes Decl. ¶ 78 (discussing study that
25 found a 9% increase in opioid-related hospitalization for each one morphine kilogram
26 equivalent [1,000 times MME] increase in opioids sales); *see also* Lembke Decl. ¶¶ 8–9,
27 146–47, 154–55, 162 (discussing causal relationship between prescription opioid supply
28 and opioid-related harm, including OUD).

17.2.1.3.2. Distribution of opioids is also strongly correlated with opioid-related death. A study analyzing the entire United States from 2006 to 2014 documents that each one-pill increase in per capita pill volume was associated with 0.2 additional overdose deaths. Keyes Decl. ¶ 79. In other words, five new pills per capita mean one new overdose death.

17.2.1.3.3. The primary importance of opioid exposure in causing OUD is not undermined by the facts that there are also other risk factors for OUD, and that some people are more vulnerable to becoming addicted than others. Besides opioid exposure, other risk factors for becoming addicted include genetic, developmental, and environmental factors. *See* Lembke Decl. ¶ 4; Lembke Trial Tr. 390:8–14; Tucker Trial Tr. 2750:10–21, 2770:17–19. The best scientific evidence, which the Court accepts, is that dose and duration of prescription opioid use “far outweigh” other risk factors for addiction. Lembke Decl. ¶ 46; Lembke Trial Tr. 398:2–7.

17.2.1.4. Each of opioids’ risks is magnified and exacerbated when opioids are diverted and used outside the closed system, other than as prescribed for a legitimate medical purpose.

17.2.1.4.1. From the testimony of Walgreens’ witness Dr. Douglas Tucker that “ongoing doctor–patient collaboration and continuous professional monitoring” can “significantly reduce” opioids’ risks, the Court infers that those risks are significantly higher without physician management, when prescription opioids are used other than as prescribed for a legitimate medical purpose. Tucker Decl. ¶ 8; *see also* Tucker Trial Tr. 2767:21–2768:17 (individuals with any history of non-medical or inappropriate use of prescription opioids have a higher risk of developing a heroin problem).

17.2.1.5. Diversion causes death. Rannazzisi Dep. 427:2. Even small amounts of diverted opioids can cause serious harm. Rannazzisi Dep. 392:10–18; P-03669_00002.

1 17.2.1.6. Prescription opioids have directly caused hundreds of deaths
2 in San Francisco, many or most of which involved diversion.

3 17.2.1.6.1. From 2010 to 2019, prescription opioids
4 accounted for 868 deaths. Coffin Decl. ¶ 44; Coffin Trial Tr. 1906:12–20.

5 17.2.1.6.2. From 2010 to 2012, of the 331 opioid overdose
6 deaths in San Francisco, 310 (93.7 percent) involved prescription opioids. Coffin Decl.
7 ¶ 21.

8 17.2.1.6.3. Additional data supports the conclusion that
9 prescription opioids were the predominant cause of overdose in the early years of the
10 opioid epidemic and continue to be a major contributor to opioid-related death in San
11 Francisco. Keyes Decl. ¶¶ 117–119.

12 17.2.1.6.4. It is not plausible that all or most of these fatal
13 overdoses happened without diversion, that is, while the person was taking opioids for a
14 legitimate medical purpose. The Court infers that many or most of these deaths involved
15 the use of diverted prescription opioids for nonmedical purposes.

16 17.2.1.7. Prescription opioids have directly caused thousands of
17 emergency room visits in San Francisco, many or most of which involved diversion.

18 17.2.1.7.1. Prescription opioids were responsible for more
19 than 1,000 ED visits at ZSFG in 2020 alone. Coffin Decl. ¶ 40.

20 17.2.1.7.2. It is not plausible that all or most of these
21 emergencies arose without diversion, that is, while the person was taking opioids for a
22 legitimate medical purpose. The Court infers that many or most of these deaths involved
23 the use of diverted prescription opioids for nonmedical purposes.

24 17.2.2. Diversion of prescription opioids leads to abuse of illicit opioids
25 like heroin and fentanyl, and to the harms associated with such abuse.

26 17.2.2.1. The Court accepts the judgment of Walgreens itself, which
27 has acknowledged internally the causal connection between prescription opioid diversion
28 and illicit opioid abuse. P-25546_00008 (80% of U.S. heroin users reported misusing

1 prescription opioids first; misusers of prescription opioids “forty times more likely” to
2 abuse heroin).

3 17.2.2.2. The consensus in the fields of epidemiology, public health,
4 and addiction medicine, which the Court accepts, is that prescription opioid use leads to
5 illicit opioid use. Lembke Decl. ¶¶ 154–55, 157; Keyes Decl. ¶¶ 53–74; Keyes Trial
6 Tr. 2213:11–2219:2, 3554:2–3555:12. This consensus is reflected in the 2017 report of the
7 National Academy of Sciences, Engineering, and Medicine and in the 2019 report of the
8 Association of Schools and Programs in Public Health, a consortium of over 120 of the
9 leading public health programs at universities in California and throughout the United
10 States. *See* Lembke Decl. ¶ 154 (“A preponderance of evidence suggests that the major
11 increase in prescription opioid use beginning in the late 1990s has served as a gateway to
12 increased heroin use[.]”), ¶ 155 (“The tremendous expansion of the supply of powerful ...
13 prescription opioids led to ... the transition of many to illicit opioids, including fentanyl
14 and its analogs[.]”); *see also* Keyes Decl. ¶ 127 (quoting 2019 ASPPH report).

15 17.2.2.3. The Court accepts research finding that opioid exposure and
16 OUD show a “dose–response” relationship, that is, that greater exposure to opioids
17 increases the risk of OUD. According to one publication by the CDC, “Drug abuse and
18 overdose rates increased with longer use,” and another CDC publication stated, “Higher
19 Dosage, Higher Risk.” Lembke Decl. ¶¶ 20–23. One study showed that the odds of getting
20 addicted are 122 times greater for patients who receive opioid prescriptions from their
21 doctors for over 120 MME per day and more than 90 days, compared to persons who did
22 not receive opioid prescriptions; that the risk increases in a clear dose–response
23 relationship; and that the increased risk of addiction due to higher dose and longer
24 duration far exceeds the risk of other known factors such as prior mental health disorder
25 or prior non-opioid substance use disorder. Lembke Decl. ¶ 46; Lembke Trial Tr. 397:24–
26 398:16; Keyes Decl. ¶¶ 47–49.

27 17.2.2.4. The “natural progression” of OUD is “to seek out more
28 potent, plentiful, and cheaper forms” of opioids over time. Lembke Decl. ¶ 156. “So it is

1 not surprising that people who become addicted to prescription opioids progress to heroin
 2 and illicit fentanyl, especially as prescription opioids become more difficult to obtain.”
 3 Lembke Decl. ¶ 156; *see also* Tucker Trial Tr. 2765:7–16 (acknowledging individuals
 4 prescribed opioids for chronic pain may seek the drug illicitly from “somewhere else” if
 5 treatment was ended abruptly), 2767:21–2768:17 (individuals with any history of non-
 6 medical or inappropriate use of prescription opioids have a higher risk of developing a
 7 heroin problem).

8 17.2.2.5. Dr. Anna Lembke, an addiction specialist practicing at
 9 Stanford Hospital who has treated thousands of patients prescribed opioids for pain, treats
 10 OUD patients who originally became addicted to prescription opioids, and are now
 11 intentionally seeking out fentanyl because of its potency (and despite its lethality).
 12 Lembke Decl. ¶¶ 37, 156.

13 17.2.2.6. The Court credits the testimony of Dr. Phillip Coffin,
 14 Director of the SFDPH Center on Substance Use and Health, who testified based on his
 15 experience treating patients and researching substance use trends in San Francisco over
 16 the last decade that the majority of people using opioids, including fentanyl, in San
 17 Francisco started their opioid use with prescription opioids. Coffin Decl. ¶ 46. He further
 18 testified that he had reviewed the medical records of thousands of opioid overdose
 19 decedents and found that most of them had received an opioid prescription at some point
 20 prior to their death. Coffin Decl. ¶ 46; Coffin Trial Tr. 1906:21–1907:4, 1924:9–18.

21 17.2.2.7. In Dr. Coffin’s experience, as opioid prescriptions in San
 22 Francisco began to decline in 2010, there was a concomitant rise in heroin use. Coffin
 23 Decl. ¶¶ 11, 22–24. The Court credits this experience and finds it supports a causal
 24 relationship: prescription opioid users turned to heroin as prescription opioids became
 25 more difficult to get.

26 17.2.2.8. Approximately two thirds of the patients who present to the
 27 ZSFG ED with an opioid-related medical condition report that their addiction started with
 28 prescription opioid pills. Colwell Decl. ¶ 10.

1 17.2.2.9. This local clinical experience is consistent with numerous
 2 studies demonstrating that the most significant risk factor for heroin use is exposure to
 3 prescription opioids. Keyes Decl. ¶¶ 53–70; Coffin Decl. ¶ 46.

4 17.2.2.10. Like heroin overdoses, contemporary illicit fentanyl
 5 overdoses are a direct outgrowth of overuse of prescription opioids. The primary effect of
 6 illicit fentanyl was to increase the mortality rate for persons suffering from OUD that
 7 resulted from overuse of prescription pills. The trend parallels the earlier shift to heroin,
 8 but has a higher death rate. Coffin Decl. ¶¶ 41–42, 44–47; Keyes Decl. ¶¶ 71–74.

9 17.2.2.11. On a market level, the shift to illicit fentanyl was driven by
 10 high demand for opioids that began with prescription pills. Persons with OUD in San
 11 Francisco do not favor fentanyl, but drug suppliers introduced them to it as demand for
 12 heroin (during the apex of the pills-to-heroin shift) exceeded the available supply. From
 13 there, economies of scale and supply and demand factors drove a broader shift from
 14 heroin to fentanyl. Coffin Decl. ¶¶ 34–37.

15 17.2.3. Diverted prescription opioids figure so prominently in the opioid
 16 epidemic that the Court infers the epidemic would have been substantially reduced in
 17 intensity or duration without them.

18 17.2.3.1. In their efforts to mitigate the opioid epidemic, City
 19 personnel frequently encounter prescription opioid use in San Francisco that is self-
 20 evidently non-medical, not for a legitimate medical purpose, and outside the closed
 21 system of opioid distribution. *See* paras. 8–9, *supra*.

22 17.2.3.2. Since the late 1990s, opioid prescriptions and prescription
 23 opioid use in San Francisco has increased substantially. *See* Keller Decl. ¶¶ 8–10 (“From
 24 1997 to 2007, dosage units prescribed by physicians in San Francisco County doubled and
 25 prescribed MMEs more than quadrupled.”). Between the late 1990s and 2010, there was
 26 fourfold increase nationally in opioid prescribing and dispensing. Lembke Decl. ¶¶ 8–11;
 27 Lembke Trial Tr. 408:19–409:1. In the 2000s, San Francisco saw a significant increase in
 28

1 the supply of prescription opioids and the number of people who used opioids. Coffin
2 Decl. ¶¶ 17–19.

3 17.2.3.3. By the mid-2000s, according to DEA officials (whose
4 judgment the Court accepts), the opioid supply chain nationwide was “out of control,” and
5 fueled a nationwide public health crisis of prescription opioid diversion. Rannazzisi Dep.
6 416:9–417:9, 423:12–426:4, 431:14–18, 433:17–434:9; P-03669; *see also* P-00139_00001
7 (Ed Bratton e-mail stating that Walgreens’ failure to provide effective controls against
8 diversion by shipping suspicious orders “without limit or review” caused “runaway
9 growth” of prescription opioid dispensing); P-23068_00002, 00007 (2015 NABP
10 stakeholder consensus statement, *see* P-20790_00001, identifying “the misuse and abuse
11 of prescription medications ... as a growing public health problem”; describing “deeply
12 concerning rise in various measures of prescription drug misuse and abuse” “[i]n parallel
13 with [an] increase in medical use” of prescription opioids).

14 17.2.3.4. From the growth in the prescription opioid supply and
15 subsequent diversion crisis, the Court infers that the growth in the opioid supply was
16 accompanied by a proportional rise in diversion.

17 17.2.3.5. In San Francisco from 2010 to 2012, among all opioid deaths,
18 prescription opioids were the most frequently listed cause of opioid death, including
19 oxycodone (21.8 percent) and hydrocodone (16.3 percent). Keyes Decl. ¶ 106; Coffin
20 Decl. ¶ 21.

21 17.2.3.6. High-volume prescribers who prescribe opioids solely for
22 profit and without a legitimate medical purpose, often called “pill mills,” inflicted
23 considerable damage nationwide through the 2000s. Keyes Decl. ¶ 88. Such prescribers
24 existed in San Francisco well into the 2010s. *See* para. 17.1.11, *supra*.

25 17.2.4. The present extent of the opioid epidemic cannot be explained
26 solely by the abuse of illicit opioids such as heroin and fentanyl, unconnected to
27 prescription opioid diversion.
28

17.2.4.1. The Court credits the testimony of Dr. Philip Coffin, who testified that the majority of opioid use in San Francisco, including fentanyl use, has its origin in prescription opioid use. Coffin Decl. ¶ 46; Coffin Trial Tr. 1906:21–1907:4, 1924:9–18, 1937:4–11.

17.2.4.2. If illicit opioids explained the full extent of the opioid epidemic on their own, rates of opioid-related harm in San Francisco would have declined from approximately 2000 to 2010 in light of the City’s successful efforts to mitigate the effects of heroin abuse. Instead those rates remained relatively stable, as decreasing heroin-related harms were replaced by increasing prescription opioid-related harms. Further, illicit opioids on their own cannot explain the rise in heroin- and then fentanyl-related harms beginning in 2010.

17.2.4.2.1. In California, from 1999 to 2018, prescription opioids were the largest contributor to the increase in overdose deaths, over other opioids such as heroin. Despite an ongoing heroin and fentanyl crisis that has accelerated the opioid epidemic, the contribution of prescription opioids to deaths in California remains significant. Keyes Decl. ¶ 116; Coffin Decl. ¶ 44.

17.2.4.2.2. In the 1990s, heroin was a significant issue in San Francisco. To address the impact of heroin, the City pioneered an array of new programs that succeeded in decreasing the rate of heroin overdose deaths substantially by 2010. In the 2000s, as national attitudes to prescription opioid use shifted, San Francisco saw a significant increase in the supply of prescription opioids and the number of people who used opioids. As a result of the increasingly large supply of prescription opioids, the number of people using prescription opioids in San Francisco increased significantly. However, unlike other places, San Francisco did not see an increase in overall opioid overdose mortality. The City continued to have success at lowering the proportion of opioid users who died from overdoses through its extensive harm reduction efforts, including naloxone distribution. Coffin Decl. ¶¶ 11–19; Coffin Trial Tr. 1896:20–1899:10.

17.2.4.2.3. The increase in supply was followed by a subsequent decline around 2010, when opioid prescribing in San Francisco waned as doctors became more aware of opioids’ risks. However, individuals who had developed dependence on opioids years earlier still were dependent on opioids to avoid the painful consequences of withdrawal. Accordingly, as prescription opioids became harder to obtain legally, many sought through the street market what was no longer available and plentiful through legal channels. Therefore, as prescription opioid use and overdose deaths decreased in San Francisco, heroin use—and heroin overdose deaths—began to increase. But San Francisco kept overdose deaths stable thanks to the efforts made by San Francisco service providers, health care providers, and residents to—among other interventions—broadly distribute and utilize naloxone to reverse overdose deaths. Coffin Decl. ¶¶ 20–30; Coffin Trial Tr. 1899:7–1900:7.

17.2.4.2.4. As the opioid epidemic developed, San Francisco did ultimately witness a marked increase in opioid mortality as large numbers of individuals who developed OUD in the 2000s turned to fentanyl. Coffin Decl. ¶¶ 11–33; P-22446; P-22447. Data from San Francisco indicates that fentanyl mortality began increasing after 2015, with especially rapid increases after 2017; the increase in fentanyl mortality deaths can be largely attributed to the oversupply of prescription opioids that began in the 1990s and continues to the present time. Keyes Decl. ¶¶ 124–25. Because of fentanyl’s potency and the rapid onset of overdose, the City was no longer able to control the opioid mortality rate with naloxone and OUD treatment options. Coffin Decl. ¶¶ 37–39.

17.2.4.3. The consensus in the field, which the Court accepts, is expressed by the 2019 Task Force Report of the Association of Schools and Programs in Public Health (ASPPH), a consortium of over 120 of the leading institutions in the United States. The ASPPH report stated, “The tremendous expansion of the supply of powerful (high-potency as well as long-acting) prescription opioids led to scaled increases in prescription opioid dependence, and the transition of many to illicit opioids, including

1 fentanyl and its analogs, which have subsequently driven exponential increases in
2 overdose.” Lembke Decl. ¶ 155; Keyes Decl. ¶ 24.

3 17.2.4.4. While there has been an obvious recent spike in deaths
4 related to heroin and illicit fentanyl, the number of deaths caused by non-fentanyl
5 prescription opioids has continued to be unacceptably high, and approximately four times
6 greater than in 1999. Lembke Decl. ¶ 152; Keyes Decl. ¶¶ 115–19; Coffin Decl. ¶ 44.

7 17.2.4.5. The Court does not credit the weakly supported suggestion
8 that the opioid epidemic is explained by a general crisis of increasing recreational drug
9 use since the late 1970s. *Contra* Tucker Trial Tr. 2758:9–2760:1; *see* Keyes Rebuttal
10 Decl. 4–10 (explaining that Dr. Tucker’s opinion rests on misreading of his sources and
11 otherwise contrary to the best research).

12 17.2.4.6. Walgreens’ dispensing of illegitimate opioid prescriptions
13 was undoubtedly not the only cause of the opioid epidemic and the nuisance that exists in
14 San Francisco. Other factors, including the aggressive and misleading promotion of
15 prescription opioids by opioid manufacturers, may well have contributed to the crisis.
16 Changes in medical practice in the 1990s, and changes in the understanding of the proper
17 role of prescription opioids for medical treatment, however, have nothing to do with the
18 dispensing of *illegitimate* prescriptions not for medical use. At no time was such non-
19 medical use encouraged or endorsed. On the contrary, at all times the medical community
20 recognized that diverted opioids and non-medical use of prescription opioids present very
21 real dangers to individuals and communities. *Cf.* Tucker Trial Tr. 2768:4–17; P-
22 23068_00002, 00007 (2015 NABP stakeholder consensus statement, *see* P-20790_00001,
23 identifying “the misuse and abuse of prescription medications ... as a growing public
24 health problem”; describing “deeply concerning rise in various measures of prescription
25 drug misuse and abuse” “[i]n parallel with [an] increase in medical use” of prescription
26 opioids). The issue here is not whether increases in legitimate prescriptions may have
27 played a role in the creating or maintaining the opioid epidemic, but rather whether the
28

1 dispensing of illegitimate prescriptions, and the diversion associated with it, also were
2 substantial factors in bringing about this epidemic.

3 17.2.4.7. In light of the significant contribution of Walgreens' conduct
4 to prescription opioid diversion in San Francisco, *see* para. 17.1, *supra*, and the significant
5 contribution of prescription opioid diversion to the opioid epidemic, *see* para. 17.2, *supra*,
6 the Court finds that Walgreens' conduct was a substantial factor in bringing about the
7 opioid epidemic, without which that epidemic would have been of lower intensity or
8 shorter duration.

9 **VI. Proximate Causation**

10 **18.** The opioid epidemic was a foreseeable consequence of prescription opioid
11 diversion in San Francisco.

12 18.1. Prescription opioids are controlled substances subject to the closed system
13 of distribution precisely because of the known risks of prescription opioid diversion. *See*
14 para. 5.2.2, *supra*.

15 18.2. Historically, uncontrolled or loosely controlled opioid use has led to public
16 health crises recognized by governments and healthcare professionals. *See* paras. 5–6,
17 *supra*.

18 18.3. The actions of others, such as drug dealers, in diverting or selling opioids,
19 is entirely foreseeable in the context of the CSA, which exists precisely to prevent such
20 foreseeable conduct. *See* para. 5.2.2, *supra*.

21 18.4. The transition of users with OUD from prescription opioids to illicit
22 opioids is a foreseeable consequence of prescription opioid diversion. *See* para. 17.2.2,
23 *supra*.

24 **19.** Prescription opioid diversion in San Francisco is not unduly remote from the
25 opioid epidemic.

26 19.1. Prescription opioid diversion is itself an integral, ongoing part of the
27 opioid epidemic. *See* paras. 17.2.1, 17.2.3, *supra*.

19.2. The connection between prescription opioid use (no matter whether the prescription opioids were diverted) and use of illicit heroin and fentanyl is physiologically and behaviorally a close one, and are driven by the same physiological and behavioral processes. *See* para. 4, *supra*.

VII. Unreasonable Interference

20. The interference with public rights described above is unreasonable. The seriousness of the harms outweighs any social utility of Walgreens' conduct. The Court examines the three nonexclusive factors set forth in the Restatement (Second) of Torts to determine the unreasonableness of the interference with public rights.

20.1. Walgreens' conduct is proscribed by the CSA and its regulations. *See* 27.3.1, *infra*.

20.1.1. The CSA proscribes the distribution or dispensing of controlled substances other than in accordance with the provisions of the statute and its regulations.

20.1.2. The CSA requires Walgreens to maintain effective controls against diversion in both its distribution and dispensing activities. As discussed above, Walgreens failed to maintain such controls at both the distribution and dispensing levels. That failure constituted a violation of the CSA.

20.1.3. The CSA required Walgreens, in its capacity as a distributor, to design and operate a system to identify suspicious orders and to report such orders to the DEA when identified. As described above, Walgreens failed to design and operate such a system and failed to identify suspicious orders. That failure constituted a violation of the CSA.

20.1.4. The CSA required Walgreens in its capacity as a distributor to halt the shipment of suspicious orders unless and until it could determine, through reasonable inquiry, that the order was not likely to be diverted. As described above, Walgreens shipped suspicious orders without engaging in any due diligence. That conduct violated the CSA.

1 20.1.5. The CSA required Walgreens to dispense only prescriptions that
 2 were issued for legitimate medical purposes. Walgreens failed to implement a system to
 3 ensure that it would dispense only prescriptions that met that criterion. That conduct
 4 violated the CSA. To the extent that Walgreens in fact dispensed prescriptions that were
 5 not issued for a legitimate medical purpose, as discussed below, that failure also violated
 6 the CSA.

7 20.1.6. The CSA represents a balance struck by Congress and by the DEA
 8 between the social utility of prescription opioids in relieving pain and the harms to
 9 individuals and communities from diversion, misuse, abuse, and OUD. Congress and the
 10 DEA have determined that the social utility of controlled substances outweighs the harms
 11 of the drugs *only* when the drugs are distributed and dispensed in accordance with the
 12 requirements of the CSA. Distribution and dispensing without compliance with these
 13 requirements is outside the balance struck by Congress and the DEA.

14 20.2. Walgreens' conduct was of a continuing nature, produced a long-lasting
 15 effect, and Walgreens knew or had reason to know, has had a significant effect on the
 16 public right.

17 20.2.1. Walgreens distributed prescription opioids for decades before it
 18 stopped. *See* para. 13.1, *supra*.

19 20.2.2. Walgreens has dispensed prescription opioids for decades and is
 20 continuing to the present to dispense them. *See* para. 15.1, *supra*.

21 20.2.3. The opioid epidemic has existed in San Francisco for at least ten
 22 years. Its effect has been long-lasting. *See* paras. 8–9, *supra*.

23 20.2.4. Walgreens knew the hazards to the public posed by its conduct.

24 20.2.4.1. Walgreens knew the hazards posed by prescription opioid
 25 diversion.

26 20.2.4.1.1. The hazards of prescription opioid diversion are so
 27 obvious that it is implausible Walgreens, a nationally significant participant in the
 28

1 healthcare industry under an obligation to prevent prescription opioid diversion, did not
2 know of them. *See* paras. 5–6, *supra*.

3 20.2.4.1.2. The DEA’s 2006 letter to all distributors,
4 including Walgreens, stated that “As each of you is *undoubtedly aware*, the abuse
5 (nonmedical use) of controlled prescription drugs is a serious and growing health problem
6 in this country.” P-00035_00005 (emphasis added).

7 20.2.4.1.3. Walgreens knew the strength of the causal
8 connection between prescription opioids and heroin, explaining in a 2017 training
9 presentation that “[n]early 80% of Americans using Heroin reported misusing opioids
10 first” and that “[i]ndividuals who misuse prescription opioid pain pills are forty times
11 more likely to abuse heroin.” P-25546_00008; *see also* P-19656_00051 (2012 DEA
12 presentation in Walgreens’ possession showing “Circle of Addiction” cycling from
13 hydrocodone, to oxycodone, to OxyContin, to heroin).

14 20.2.4.2. Walgreens knew its conduct was leading and would lead to
15 prescription opioid diversion.

16 20.2.4.2.1. The number of suspicious wholesale orders
17 Walgreens received from its pharmacies in San Francisco was sufficient to alert
18 Walgreens to the likelihood that prescription opioids were being diverted from at least
19 some of its stores in San Francisco.

20 20.2.4.2.2. Walgreens’ knew through its dispensing data
21 analyses that several opioid prescribers like Guido Gores and Andrew Giovannini were
22 suspicious, high-volume outliers, but continued dispensing their opioid prescriptions. *See*
23 para. 17.1.11, *supra*.

24 20.2.4.2.3. Walgreen knew through the observations,
25 comments, and warnings of their own pharmacists that opioid prescribers like Guido
26 Gores and Andrew Giovannini were too dangerous to dispense for, but did not warn, or
27 provide a mechanism for its pharmacists to warn, its pharmacies and pharmacists in the
28

1 area. Instead, Walgreens continued dispensing their opioid prescriptions. *See* 17.1.11,
 2 *supra*.

3 20.2.4.2.4. Walgreens knew through official channels that
 4 opioid prescribers like John Pierce and Ray Seet were restricted from opioid prescribing
 5 or barred from the practice of medicine, but continued dispensing their opioid
 6 prescriptions. *See* 17.1.11, *supra*.

7 20.2.4.2.5. When it came to “high prescribing physicians”
 8 like these doctors, Walgreens knew that failing (as it did, *see* para. 16.2.6, *supra*) to
 9 implement a chain-wide prescriber blocking system presented risks that were “too great.”
 10 P-20639 _ 00009 (presentation authored by Tasha Polster).

11 20.2.4.2.6. The DEA warned Walgreens executives (among
 12 other national retail pharmacy executives) in a November 2012 presentation on
 13 “Prescription Drug Trafficking and Abuse” of the dangers of understaffing pharmacies
 14 and incentivizing dispensing speed and volume at the expense of “check[ing] ... for good
 15 faith.” P-19827_00001 to 00002. The presentation draw a direct line from failure to
 16 perform pharmacy due diligence to the national opioid epidemic. P-19827_00002 (“If a
 17 pharmacist does his job, we wouldn’t have this problem.”).

18 20.3. Walgreens’ conduct involves a significant interference with the public
 19 health and public convenience. *See* paras. 8–12, *supra*.

20 20.4. There is no social utility to conduct that is proscribed by statute or
 21 regulation. There is no social utility to diverted opioids. Opioids have social utility only
 22 when prescribed and used for legitimate medical purposes. For this reason, the social
 23 utility of Walgreens’ conduct in distributing and dispensing prescription opioids without
 24 maintaining effective controls against diversion is outweighed by the gravity of the harm
 25 inflicted.

26 20.5. The CSA and its regulations represent a balance struck by Congress and
 27 the DEA between the social utility of opioids in the treatment of pain, and the harms to
 28 communities and people associated with controlled substance misuse, abuse, and

1 addiction. The Court finds that the distribution and dispensing of prescription opioids
 2 without compliance with the CSA falls outside the balance struck by Congress and the
 3 DEA, such that the utility of such dispensing without the safeguards prescribed by law is
 4 outweighed by the gravity of the harms.

5 20.6. Neither the California Intractable Pain Treatment Act nor the Pain
 6 Patients' Bill of Rights supports a different conclusion. Both statutes address legitimate
 7 prescriptions written for medical use. Both statutes focus on the role of practitioners in
 8 prescribing opioids for pain. Neither statute suggests that illegitimate prescriptions,
 9 diversion, or non-medical use of opioids has any social utility at all. *Cf.* paras. 26.2.2—
 10 26.2.3, *infra*.

11 20.7. To the extent that Walgreens' conduct resulted in the diversion of
 12 prescription opioids for purposes other than legitimate medical use, the seriousness of the
 13 harms of associated with such use clearly and significantly outweighs the social utility of
 14 Walgreens' distribution and dispensing conduct.

15 **VIII. Adverse Credibility Findings**

16 **21.** The Court does not credit evidence contrary to the above findings.

17 21.1. The Court does not credit the contrary testimony of addiction doctor
 18 Douglas Tucker. Specifically, the Court finds no basis for Dr. Tucker's opinion that, along
 19 with a clutch of other factors, the opioid epidemic is the result of a "multigenerational
 20 crisis" in American "culture," which has grown to accept "recreational pharmacology."
 21 Tucker Trial Tr. 2760:11–2762:14. The Court finds this testimony does not credibly rebut
 22 the views of the People's witnesses, on academic and observational grounds, that the
 23 opioid epidemic is caused primarily by the use and availability of opioids.

24 21.2. The Court does not credit the contrary testimony of Robert Brunner,
 25 Walgreens' data analysis expert. To the extent that Dr. Brunner criticized specific
 26 analyses performed by Dr. McCann, the Court has already concluded that even accepting
 27 Dr. Brunner's specific critique does not materially change the Court's view of the
 28 evidence. *See* para. 17.1.4.4, *supra*. And the Court has already found that it does not credit

1 Dr. Brunner’s generalized overbreadth critique of the People’s flagging methods. *See*
 2 para. 17.1.4.3, *supra*.

3 21.3. The Court does not credit the contrary testimony of Walgreens’ pharmacy
 4 expert Kathleen Hill-Besinque. Dr. Besinque’s testimony did not effectively rebut the
 5 People’s pharmacy experts Mr. Catizone and Dr. Park. Dr. Besinque consistently failed in
 6 her testimony to distinguish which situations a pharmacist should view as a “red flag,”
 7 that is, as raising suspicions prompting further inquiry, and which of a litany of
 8 hypothetical facts might be useful to a pharmacist in investigating and clearing the red
 9 flag. *See, e.g.*, Besinque Trial Tr. 2576:13–2577:24. This testimony does not answer the
 10 People’s experts’ testimony that prevailing standards of pharmacy practice view the “red
 11 flags” identified by these experts as cause for investigation. Dr. Besinque also proved
 12 unfamiliar with decisions rendered by the California State Board of Pharmacy that
 13 contradicted her testimony. *See, e.g.*, Besinque Trial Tr. 2627:9–24. Dr. Besinque’s
 14 testimony was not a reliable guide to the standard of care California imposes on
 15 pharmacies and pharmacists.

16 21.4. The Court does not credit the contrary testimony of long-time Walgreens
 17 employee, and most recently head of Walgreens “Pharmaceutical Integrity” group, Tasha
 18 Polster. The Pharmaceutical Integrity group was created at the end of 2012 in response to
 19 the DEA investigations that were resolved by settlement in the 2013 Memorandum of
 20 Agreement. *See* Polster Trial Tr. 2354:3–2356:3. But Polster did not even review most of
 21 the documents constituting the settlement, Polster Trial Tr. 2362:4–12, and so was not
 22 familiar with what Walgreens had admitted with respect to the inadequacies of its system
 23 and what it had agreed to do to address those inadequacies. Polster testified that, before
 24 the formation of Pharmaceutical Integrity, Walgreens’ SOM program “was conducted by
 25 distribution center personnel,” Polster Decl. ¶ 6, but was unable to offer any coherent
 26 basis for that testimony. *See* Polster Trial Tr. 2350:5–2353:23. Similarly, Polster admitted
 27 that she didn’t “have, like, proof” of her statement that Walgreens’ pharmacists complied
 28 with Walgreens’ GFD and TDGFD policies, but had based the statement on her belief that

1 “[p]armacists in general want to do the right thing.” *See* Polster Trial Tr. 2402:10–
 2 2405:16. Polster did not provide credible testimony rebutting the People’s contrary
 3 evidence.

4 21.5. The Court does not credit the contrary testimony of former Walgreens
 5 pharmacy supervisor and district manager Ronda Lowe. *See, e.g.*, Lowe Decl. ¶ 5. As a
 6 field leader supervising between 12 and 30 different stores, some of which were in San
 7 Francisco, Dr. Lowe’s usual practice was to visit the pharmacies approximately once a
 8 month. *See* Lowe Trial Tr. 3039:1–13. These visits were not robust or effective oversight
 9 of Walgreens’ opioid dispensing. Of the dozens of tasks outlined in the “store walk”
 10 documents Dr. Lowe referred to, just one referenced Walgreens’ Good Faith Dispensing
 11 policies, and the review it prompted was minimal. *See* Lowe Trial Tr. 3018:9–22, 3041:1–
 12 3042:8. Dr. Lowe could not say how often Walgreens pharmacists completed TDGFD
 13 checklists, Lowe Trial Tr. 3043:10–20, how often Walgreens pharmacists refused to fill
 14 opioid prescriptions, Lowe Trial Tr. 3049:1–14, or even how often or *whether* prescription
 15 opioids were diverted from Walgreens pharmacies. Lowe Trial Tr. 3089:21–3090:19. Dr.
 16 Lowe did not provide credible testimony rebutting the People’s contrary evidence.

17 **PROPOSED CONCLUSIONS OF LAW**

18 **I. Evidence**

19 **22.** In this bench trial, the Court’s findings are presumed to be based on admissible
 20 evidence. *See Williams v. Illinois*, 567 U.S. 50, 69 (2012) (“When the judge sits as the
 21 trier of fact, it is presumed that the judge ... will not rely on [inadmissible] information for
 22 any improper purpose.”); *Harris v. Rivera*, 454 U.S. 339, 465 (1981) (“In bench trials,
 23 judges routinely hear inadmissible evidence that they are presumed to ignore when
 24 making decisions.”); *Beatty v. Stewart*, 303 F.3d 975, 985 (9th Cir. 2002) (“[W]e presume
 25 that the judge properly applied the law and considered only the evidence he knew to be
 26 admissible.”). The Court therefore finds it unnecessary to rule separately on each
 27 outstanding evidentiary objection raised during trial. To the extent such objections relate
 28 to the evidence cited in support of the Court’s findings, the objections are overruled.

II. Elements of Nuisance

23. California substantive law applies to this diversity action. 28 U.S.C. § 1652.

24. The People, by and through San Francisco City Attorney David Chiu, are authorized to bring this action for abatement of a public nuisance existing within San Francisco. Cal. Civ. Code § 731.

25. A public nuisance is “[a]nything which is injurious to health ... or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property,” which “affects at the same time an entire community or neighborhood, or any considerable number of persons.” *City & County of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 669 (N.D. Cal. 2020) [hereinafter “CCSF”]; Cal. Civ. Code §§ 3479, 3480.

25.1. To prove the present existence of a public nuisance, it is not necessary to prove that the defendant’s conduct which created or contributed to the nuisance is still ongoing. A public nuisance is a “[t]hing which is injurious to” or interferes with a public right, a harmful or “hazardous condition.” Cal. Civ. Code § 3479; *People v. ConAgra Grocery Prods. Co.*, 227 Cal. Rptr. 3d 499, 535 (Ct. App. 2017). The hazardous condition created, maintained, or contributed to by the defendant’s conduct may persist decades after the conduct stopped. *See, e.g., ConAgra*, 227 Cal. Rptr. 3d at 544 (defendant liable for abatement of present nuisance “decades after all of” defendant’s nuisance-causing conduct ceased).

26. To prove a claim for public nuisance, a plaintiff must prove by a preponderance of the evidence that a defendant’s affirmative conduct was a legal cause of a substantial and objectively unreasonable interference with a right common to the public. *CCSF*, 491 F. Supp. 3d at 669–84; *People ex rel. Gallo v. Acuna*, 929 P.2d 596, 604–05 (Cal. 1997); *ConAgra*, 227 Cal. Rptr. 3d at 525–52; *see also* CACI No. 2020.

26.1. An interference is “substantial” if it causes “significant harm.” *County of Santa Clara v. Alt. Richfield Co.*, 40 Cal. Rptr. 3d 313, 325 (Ct. App. 2006) (citing *Acuna*, 929 P.2d at 604–05).

1 26.2. An interference is “unreasonable” if the harm it inflicts outweighs the
 2 social utility of the conduct causing it, viewed in light of several factors, any one of which
 3 may support a determination of unreasonableness, including nonexclusively whether the
 4 conduct was proscribed by law; whether the conduct involves a significant interference
 5 with the public health, the public safety, the public peace, the public comfort, or the public
 6 convenience; and whether the conduct is of a continuing nature or has produced a
 7 permanent or long-lasting effect, and has a significant effect on a public right of which the
 8 defendant knew or had reason to know. Restatement (Second) Torts § 821B (Am. Law
 9 Inst. 1979); *CCSF*, 491 F. Supp. 3d at 672–73; *Acuna*, 929 P.2d at 604; *ConAgra*, 227
 10 Cal. Rptr. 3d at 552.

11 26.2.1. Knowledge on the part of the defendant is a factor under the last of
 12 the three enumerated bases for a finding of unreasonable interference, but it is not an
 13 element of either of the other two. A plaintiff may demonstrate unreasonable interference
 14 through the other bases—including the breach of a legal duty, or unlawful conduct—
 15 without demonstrating knowledge on the part of the defendant.

16 26.2.1.1. In *Atlantic Richfield Co.*, 40 Cal. Rptr. 3d at 325, the court
 17 referenced the knowledge of the defendant in its analysis of the nuisance. Because the
 18 conduct in that issue was not unlawful, however, it does not appear that the court had any
 19 occasion to address whether knowledge would be required if the unreasonable prong were
 20 satisfied through unlawful conduct.

21 26.2.1.2. The California Supreme Court has never adopted a
 22 knowledge requirement for nuisance claims.

23 26.2.2. An interference that results from unlawful conduct is generally
 24 unreasonable: the harm it inflicts outweighs the social utility of the conduct because there
 25 is no social utility to unlawful conduct.

26 26.2.3. The Controlled Substances Act strikes a balance between the social
 27 utility of prescription opioids, on the one hand, and the dangers of uncontrolled use and
 28 diversion of those drugs, on the other. In permitting the manufacture, sale, distribution,

1 and dispensing of prescription opioids only in accordance with the provisions of the CSA
 2 and its regulations, Congress and the DEA have determined that the social utility of these
 3 drugs justifies their availability only when that availability is restricted as set forth in the
 4 statute and its regulations. Thus, Congress and the DEA have determined that the harms of
 5 distribution and dispensing of these drugs outside the regulatory framework outweigh the
 6 social utility of the drugs.

7 26.2.4. The Court previously held that “[p]ublic nuisance claims require the
 8 existence of a duty.” *CCSF*, 491 F. Supp. 3d at 669. That is not to hold that proof of
 9 independently unlawful conduct is always required to prove a public nuisance claim. *See*
 10 *Acuna*, 929 P.2d at 601–02 (condition constituting nuisance comprised partly of lawful
 11 and partly of unlawful conduct); *id.* at 607 (“Acts or conduct which qualify as public
 12 nuisances” so qualify “not from their status as independent crimes, but from their inherent
 13 tendency to injure or interfere with the community’s exercise and enjoyment of rights
 14 common to the public.”). The authority cited by the Court stands for the narrower
 15 proposition that engaging in lawful though “risky” behavior, “without a connecting
 16 causative link” to a “significant invasion of a public right,” does not create public
 17 nuisance liability. *In re Firearm Cases*, 24 Cal. Rptr. 3d 659, 680 (Ct. App. 2005).

18 26.3. A defendant is a legal cause of harm if the defendant’s conduct is a
 19 substantial factor in bringing it about and there is no rule of law or consideration of policy
 20 limiting the defendant’s responsibility for the consequences of its conduct and relieving it
 21 of liability. *ConAgra*, 227 Cal. Rptr. 3d at 545.

22 26.3.1. “The substantial factor standard is a relatively broad one, requiring
 23 only that the contribution of the individual cause be more than negligible or theoretical. ...
 24 [A] a force which plays only an ‘infinitesimal’ or ‘theoretical’ part in bringing about
 25 injury ... is not a substantial factor, but a very minor force that does cause harm is a
 26 substantial factor.” *ConAgra*, 227 Cal. Rptr. 3d at 543 (citations and quotation marks
 27 omitted). If a defendant’s wrongful conduct “operated concurrently with other
 28 contemporaneous forces to produce the harm, it is a substantial factor ... if the injury, or

1 its full extent, would not have occurred but for that conduct.” *In re Ethan C.*, 279 P.3d
 2 1052, 1071 (Cal. 2012). Thus, the People need demonstrate that Walgreens’ “conduct was
 3 necessary in bringing about the *full extent* of the [People’s] injuries,” *CCSF*, 491 F. Supp.
 4 3d at 677, to more than an “infinitesimal” or “theoretical” degree. *ConAgra*, 227 Cal.
 5 Rptr. 3d at 543; *cf.* W. Page Keeton *et al.*, *Prosser & Keeton on Torts* 267–68 (5th ed.
 6 1984) (discussing lighted match thrown into forest fire as example of harm causation that
 7 does not satisfy substantial factor test). The test is distinct from “but for” causation, which
 8 is not applicable here, but rather is “subsumed” in the substantial factor test. *See CCSF*,
 9 491 F.Supp. 3d at 677; CACI No. 430.

10 26.3.1.1. A defendant’s conduct may be necessary in bringing about
 11 the full extent of injury either in scope or duration or both. Thus, to prove Walgreens’
 12 conduct was necessary in bringing about the full extent of the alleged public nuisance, the
 13 People may prove either that Walgreens created, expanded, or maintained the public
 14 nuisance to more than an infinitesimal or theoretical degree. *See CCSF*, 491 F. Supp. 3d at
 15 677; *ConAgra*, 227 Cal. Rptr. 3d at 525, 543.

16 26.3.2. The doctrine of proximate cause limits liability: in certain situations
 17 where the defendant’s conduct is an actual cause of the harm, it will nevertheless be
 18 absolved because of the manner in which the injury occurred. Absent special
 19 considerations of policy, proximate cause exists where the harm is a reasonably
 20 foreseeable result of the defendant’s wrongful conduct, and not unduly remote from
 21 defendant’s wrongful conduct. *CCSF*, 491 F. Supp. 3d at 679; *ConAgra*, 227 Cal. Rptr. 3d
 22 at 545.

23 26.3.2.1. In the context of nuisance, proximate cause does not require a
 24 direct relationship between the conduct and the injury. Rather, it is sufficient that “the
 25 defendant’s conduct is likely to cause a significant invasion of a public right.” *CCSF*, 491
 26 F. Supp. 3d at 679.

27 26.3.2.2. The Court previously held that harms flowing from discarded
 28 needles are not foreseeable as a matter of law. *CCSF*, 491 F. Supp. 3d at 656, 658, 679. In

1 light of the evidence at trial showing a well known, historically recognized, and intuitively
 2 plausible causal relationship between increased prescription opioid use and increased
 3 illicit injection of opioids, the Court reconsiders that ruling and holds that harms flowing
 4 from discarded needles may be foreseeable consequences of Defendants' conduct as a
 5 matter of law.

6 26.3.3. Causation may be proved in the aggregate as a matter of law. There
 7 is no state or federal rule requiring the People to prove that specific individual
 8 prescriptions contributed to the alleged public nuisance. Indeed, California courts have
 9 repeatedly rejected the requirement of individualized proof and have upheld the use of
 10 aggregate proof. *See, e.g., Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 663–64 (Cal.
 11 1973) (proof of specific exposure to misrepresentations not required); *City of Modesto v.*
 12 *Dow Chem. Co.*, 227 Cal. Rptr. 3d 764, 783-84 (Ct. App. 2018) (individualized proof not
 13 required; fact finder can consider all of defendant's conduct together); *ConAgra*, 227 Cal.
 14 Rptr. 3d at 557 (no requirement to prove specific promotions caused presence of lead
 15 paint in specific houses); *State ex rel. Wilson v. Super. Ct.*, 227 Cal. Rptr. 3d 764, 783-84
 16 (Ct. App. 2014) (proof of causation need not be prescription by prescription); *see also In*
 17 *re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 45 (1st Cir. 2013).

18 26.4. It is no bar to a public nuisance claim that the alleged public nuisance may
 19 be characterized as a complex social problem amenable to policy solutions by the
 20 legislative and executive branches of government. Public nuisance law “protect[s] the
 21 quality of organized social life.” *Acuna*, 929 P.2d at 604. A problem as complex and
 22 multifaceted as urban deterioration caused by gang activity may qualify as a public
 23 nuisance, though also the subject of special legislation. *See id.* at 601–602, 614. There is
 24 no basis in law or reason to exempt the opioid epidemic in San Francisco from the broad
 25 reach of the public nuisance statutes. *See* Cal. Civ. Code §§ 3479, 3480.

26 26.5. The statement of the court in *City of Huntington v. AmerisourceBergen*
 27 *Drug Corporation*, No. CV 3:17-01362, 2022 WL 2399876, at *57 (S.D.W. Va. July 4,
 28 2022), that “[t]he extension of the law of nuisance to cover the marketing and sale of

opioids is inconsistent with the history and traditional notions of nuisance,” is inapplicable in this case because, among other reasons, *City of Huntington* was decided under West Virginia law. California law, as set forth in *ConAgra* and elsewhere takes a broader view of nuisance than the *City of Huntington* court believed was the case under West Virginia law. Compare, e.g., *City of Huntington*, 2022 WL 2399876, at *59 (applying *In re Lead Paint Litig.*, 924 A.2d 484, 505 (N.J. 2004) (rejecting public nuisance liability “for the sale and distribution of a product” like lead paint)), with *ConAgra*, 227 Cal. Rptr. 3d at 594 (affirming public nuisance liability for lead paint); compare also, e.g., *City of Huntington*, 2022 WL 2399876, at *57 (applying Restatement (Third) of Torts § 8 cmt. g), with *Acuna*, 929 P.2d at 604–05 (discussing close relationship between California nuisance statutes and Restatement (Second) of Torts § 821B).

III. Proof of Nuisance Elements

27. The People have proved their public nuisance claim against Walgreens.

27.1. The People have proved an interference with rights common to the public because the opioid epidemic interferes with the public health, public safety, and public convenience in San Francisco. *See* paras. 8–9, *supra*.

27.2. The People have proved a substantial inference with a public right because the opioid epidemic has caused and is causing significant harm in San Francisco. *See* para. 12, *supra*.

27.3. The People have proved an unreasonable interference with a public right because the harm caused by Walgreens’ conduct outweighs its social utility.

27.3.1. The People have proved that Walgreens’ conduct, insofar as it was a legal cause of the interference, was proscribed by federal and California law. *See* paras. 14, 16, *supra*.

27.3.1.1. The CSA makes it unlawful to “to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance” except as authorized by the CSA and its regulations. 21 U.S.C. § 841(a).

1 Distribution or dispensing of prescription opioids without complying with the
2 requirements of the CSA is thus proscribed by statute.

3 27.3.1.2. As valid regulations to enforce the CSA, 21 C.F.R.
4 §§ 1301.71(a) and 1301.74(b) impose legal duties on DEA registrants to identify, report,
5 and refrain from shipping suspicious orders of prescription opioids. *CCSF*, 491 F. Supp.
6 3d at 631–32 (citing *In re Nat’l Prescription Opiate Litig.*, 1:17-md-2804, 2019 WL
7 3917575, at *7–9 (N.D. Ohio Aug. 19, 2019)).

8 27.3.1.3. As a valid regulation to enforce the CSA, 21 C.F.R.
9 § 1301.71(a) requires DEA registrants not to ship suspicious orders of prescription opioids
10 before determining through reasonable inquiry that the orders are not likely to be diverted.
11 *CCSF*, 491 F. Supp. 3d at 632 (citing *In re Nat’l Prescription Opiate Litig.*, 2019 WL
12 3917575, at *8); *see also Masters Pharm. Inc. v. DEA*, 861 F.3d 206, 212–13 (D.C. Cir.
13 2013) (citing *Southwood Pharm. Inc.*, 72 Fed. Reg. 36,487, 36,501, 2007 WL 1886484
14 (DEA July 3, 2007)).

15 27.3.1.4. Shipping suspicious orders of prescription opioids without
16 inquiry is unambiguously not an “effective” means to prevent diversion and theft of
17 prescription opioids by the plain terms of the regulation. 21 C.F.R. § 1301.71(a).

18 27.3.1.5. Even if it were ambiguous whether shipping suspicious
19 orders of prescription opioids without inquiry is an “effective” means to prevent diversion
20 and theft of prescription opioids by the terms of the regulation, the Court would defer to
21 the DEA’s reasonable interpretation of “effective” to exclude shipping without inquiry
22 because it is the DEA’s official view, implicates the DEA’s substantive expertise in
23 preventing controlled substances diversion, and embodies the DEA’s fair and considered
24 judgment. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2414–18 (2019).

25 27.3.1.6. 21 C.F.R. § 1306.04(a) imposes as a legal duty on
26 pharmacies, pharmacists, and pharmacy owners a “corresponding responsibility,”
27 corresponding to the prescriber’s responsibility, “for the proper prescribing and
28 dispensing” of prescription opioids. *See also CCSF*, 491 F. Supp. 3d at 669–70.

Specifically, section 1306.04(a) proscribes the dispensing of prescription opioids except when filling a prescription “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” *See also CCSF*, 491 F. Supp. 3d at 669–70.

27.3.1.7. As established by expert evidence, *see Miller v. Los Angeles County Flood Control Dist.*, 505 P.2d 193, 201–02 (Cal. 1973), complying with this requirement requires the investigation, resolution, and documentation of resolution of objective warning signs or “red flags” of diversion before a prescription opioid is dispensed. *See paras. 15.5–15.8, supra.*

27.3.1.8. The content of the corresponding responsibility imposed by § 1306.04 is supplied in part by state law and state standards of care. *See Pharmacy Doctors Enters., Inc. v. DEA*, 789 F. App’x 724, 731 (11th Cir. 2019) (affirming DEA order revoking pharmacy’s registration; holding that pharmacy’s failure to comply with jurisdiction’s “prevailing professional standard,” which required pharmacists to “document their resolution of red flags,” was “part and parcel” of pharmacy’s corresponding responsibility failure).

27.3.1.9. As established by expert evidence, *see Miller*, 505 P.2d at 201–02, the standard of care for pharmacy practice in California requires both red flag due diligence and compliance with pharmacy policy.

27.3.1.9.1. California law imposes a standard of care on pharmacists and pharmacies in the dispensing of prescription opioids. That standard requires the investigation, resolution, and documentation of resolution of objective warning signs or “red flags” of diversion before a prescription opioid is dispensed. *See paras. 15.5–15.8, supra; see also In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran*, Bd. of Pharmacy Case No. 3802, OAH No. 2011010644, Precedential Decision No. 2013-01, at 24–35 (Cal. Bd. of Pharmacy Aug. 5, 2013 (made precedential), Apr. 4, 2012 (decided)) (“The corresponding responsibility law is both a standard of care and a duty recognized by statute.”). Proving violation of the California

1 corresponding responsibility law does not require establishing that “any particular
2 prescription ... was written for an illegitimate purpose” where the “nature and extent of the
3 red flags” that went unresolved are serious and widespread. *Id.* at 35.

4 27.3.1.9.2. The standard of care in California requires
5 pharmacies to follow their own policies and procedures. *In the Matter of the Third*
6 *Amended Accusation Against IV Sols. Inc.; Alireza Varatehpour; Renee Sadow*, Bd. of
7 Pharmacy Case No. 3606, OAH No. 2011050988, Precedential Decision No. 2020-01, at
8 44 (Cal. Bd. of Pharmacy Oct. 20, 2020 (made precedential), Apr. 17, 2015 (decided))
9 (“Respondent [pharmacy] had a duty to follow its own policies and procedures,” despite
10 those policies not having the force of law.).

11 27.3.1.10. To prove an unreasonable interference by conduct that is
12 proscribed by law, it is not necessary for the People to show that Walgreens or any of its
13 pharmacies or pharmacists knowingly filled opioid prescriptions not for a legitimate
14 medical purpose. That is required to impose penal liability under the CSA’s enforcement
15 provisions. *See* 21 C.F.R. § 1306.04(a) (“[T]he person *knowingly* filling such a purported
16 prescription [issued not in the usual course of professional treatment or in legitimate and
17 authorized research] *shall be subject to the penalties provided* for violations of the
18 provisions of law relating to controlled substances.” (emphasis added)). It is not required
19 to prove under California public nuisance law that Walgreens’ conduct produced an
20 “unreasonable” interference with a public right because the conduct was “proscribed by a
21 statute, ordinance[, or administrative regulation” and thus in breach of a legal duty.
22 *CCSF*, 491 F. Supp. 3d at 672 (quoting Restatement (Second) of Torts § 821B(2)(b)); *cf.*
23 *Pacifica*, at 35 (violation of California corresponding responsibility law does not require
24 establishing that “any particular prescription ... was written for an illegitimate purpose”).

25 27.3.2. The People have proved that Walgreens’ conduct, insofar as it was a
26 legal cause of the interference, involved a significant interference with the public health
27 and the public convenience. *See* paras. 8–12, 20.2, *supra*.

1 27.3.3. The People have proved that Walgreens’ conduct, insofar as it was a
 2 legal cause of the interference, is of a continuing nature, has produced long-last effects,
 3 and has had significant effects on public rights of which Walgreens knew or had reason to
 4 know. *See* para. 20.2, *supra*.

5 27.3.4. The People have proved that the social utility of Walgreens’
 6 conduct in distributing and dispensing prescription opioids in the manner described above
 7 is outweighed by the gravity of the harm inflicted by that conduct.

8 27.3.4.1. Neither the California State Assembly, Congress, nor the
 9 DEA has determined that there is any social utility to opioids diverted for non-medical
 10 use. Nor could the California legislature have made such a determination. As reflected in
 11 the CSA, the federal government long ago determined that diverted opioids present
 12 sufficient dangers to individuals and communities that the manufacture, distribution,
 13 dispensing and sale of these drugs must be tightly controlled in order to prevent diversion.
 14 *See generally* 21 U.S.C. §§ 801–971; *see also* 21 U.S.C. § 801(2) (“The illegal
 15 importation, manufacture, distribution, and possession and improper use of controlled
 16 substances have a substantial and detrimental effect on the health and general welfare of
 17 the American people.”); H.R. Rep. 91-1444 (1970), 1970 U.S.C.C.A.N. 4566, 4571–72
 18 (noting concerns about “diversions [of regulated drugs] from legitimate channels” and the
 19 dangers that regulated drugs pose to the “safety of the community”); 21 C.F.R.
 20 § 1301.71(a) (requiring all CSA registrants to “provide effective controls and procedures
 21 to guard against theft and diversion of controlled substances”). The CSA thus makes clear
 22 that the failure to provide effective controls against diversion results in a substantial
 23 interference with public health and welfare and thus can constitute a public nuisance.

24 27.3.4.2. Because the public nuisance the People assert Walgreens
 25 created or participated in creating derives from the diversion of prescription opioids, the
 26 People need not show that the nuisance is driven by, or includes, medically inappropriate
 27 prescriptions. The diversion of opioids from legitimate medical purposes is an
 28 independently wrongful and a factually distinct cause of the opioid epidemic. *See* para.

1 17.2, *supra*. Regardless of the social utility of medically appropriate opioid prescriptions,
 2 there is no social utility to diverted opioids used not for a legitimate medical purpose. *See*
 3 paras. 26.2.2–26.2.3, *supra*.

4 27.3.4.2.1. The statement of the court in *City of Huntington*
 5 that “the distribution of medicine to support the legitimate medical needs of patients as
 6 determined by doctors exercising their medical judgment in good faith cannot be deemed
 7 an unreasonable interference with a right common to the general public,” 2022 WL
 8 2399876, at *60, is inapplicable in this case because it does not address the question of
 9 diverted opioids, which are, by definition, used non-medically.

10 27.3.4.2.2. Similarly, the statement of the court in *People v.*
 11 *Purdue Pharma L.P.*, No. 30-2014-00725287-CU-BT-CXC, 2021 WL 5227329, at *7
 12 (Cal. Super. Ct. Nov. 1, 2021) (emphasis omitted) [hereinafter “*Santa Clara*”], that “any
 13 adverse downstream consequences flowing from medically appropriate prescriptions
 14 cannot constitute an actionable public nuisance” is inapplicable in this case. The question
 15 whether a prescription is issued for a “legitimate medical purpose” within the meaning of
 16 the CSA and its regulations is distinct from whether the prescription is medically
 17 appropriate. Under the CSA, Walgreens was required both to limit its dispensing to valid
 18 prescriptions written for a legitimate medical purpose and to provide effective controls
 19 against diversion. The question whether a prescription is medically appropriate does not
 20 arise when the prescription is not written or filled for a medical purpose at all. The court
 21 in *Santa Clara* had no occasion to make that distinction because the claims there did not
 22 involve distribution or dispensing of opioids; rather, the plaintiff there asserted that
 23 defendants’ misleading promotion of opioids caused doctors to write prescriptions they
 24 would not have written in the absence of the defendants’ misrepresentations.

25 27.3.4.2.3. For this reason, it is not necessary for the People
 26 to show that a single prescription was ever medically inappropriate as written in order to
 27 show that Walgreens’ failure to provide effective controls against diversion created,
 28 contributed to, or maintained a public nuisance in San Francisco. Diverted drugs are

1 sufficient, in and of themselves as a matter of law, to create, contribute to, or maintain
2 such a nuisance.

3 27.4. The People have proved that Walgreens was a substantial factor in
4 bringing about the opioid epidemic in San Francisco. *See* para. 17, *supra*.

5 27.5. Because the People have proved that the opioid epidemic was a
6 foreseeable and not unduly remote consequence of Walgreens' contribution to
7 prescription opioid diversion in San Francisco, and because the Court finds no rule of law
8 or consideration of policy limiting Walgreens' responsibility for the consequences of its
9 conduct, the People have proved that Walgreens was a proximate cause of the opioid
10 epidemic in San Francisco. *See* para. 18, *supra*.

11 27.6. Actual knowledge, even if required, may be shown exclusively through
12 circumstantial evidence and reasonable inferences from the circumstantial evidence.
13 *ConAgra*, 227 Cal. Rptr. 3d at 530. Even if required, the People have proved it through
14 multiple types of evidence, including, among other things, evidence that Walgreens was
15 informed by the DEA of the risks and consequences of improper distribution and
16 dispensing. *See* para. 20.2.4, *supra*.

17 **IV. Failure of Affirmative Defenses**

18 **28.** Federal law does not preempt the People's public nuisance claim.

19 28.1. The CSA contains an express savings clause providing that the CSA "shall
20 [not] be construed as indicating an intent on the part of Congress to occupy the field ... to
21 the exclusion of any State law on the same subject matter which would otherwise be
22 within the authority of the State, unless there is a *positive conflict*" 21 U.S.C. § 903.
23 Section 903 "precludes any argument that Congress intended to preempt state laws that
24 enforce the CSA absent a positive conflict," and "[n]o such conflict exists" here. *CCSF*,
25 491 F. Supp. 3d at 662.

26 28.2. Under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001),
27 state law claims are preempted to the extent that federal law is a "critical element" that is
28 essential to the state claim.

1 28.3. State law claims that are not based on a “fraud-on-the-agency” theory, but
 2 that instead rely on traditional state law principles that parallel, rather than obstruct,
 3 federal duties are generally not preempted. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470,
 4 495 (1996); *see also Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (*en*
 5 *banc*).

6 28.4. The People do not invoke a fraud-on-the-DEA theory. *See In re Nat’l*
 7 *Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4178591, at *5, *12 (N.D. Ohio
 8 Sept. 3, 2019). Although the People’s public nuisance claim involves Walgreens violating
 9 its duties under CSA and its implementing regulations, including failing to monitor and
 10 report suspicious orders to the DEA, as one means of establishing its public nuisance
 11 liability, such violations are not a “critical element” of a public nuisance claim under
 12 California state law.

13 28.5. Mere overlap between Walgreens’ duties under federal and state law does
 14 not amount to dependence. *CCSF*, 491 F. Supp. 3d at 665 (“Overlap should not be
 15 mistaken for dependence.”). The People seek to enforce state law that imposes duties
 16 distinct from the CSA and that would exist absent the CSA. Walgreens’ duty, under
 17 California law, not to substantially contribute to an injurious condition that unreasonably
 18 interferes with rights common to the public exists independent from Walgreens’ federal
 19 duties under the CSA.

20 28.6. Because the People’s public nuisance claim is premised on independent
 21 state common law duties that parallel, and do not conflict with, the duties created under
 22 the CSA, *Buckman* and its progeny are inapposite. *See Stengel*, 704 F.3d at 1233.

23 28.7. For the same reasons, the Supreme Court’s decision in *Astra USA, Inc. v.*
 24 *Santa Clara County*, 563 U.S. 110 (2011), which did not deal with state law claims that
 25 exist separately and independently of the subject federal statute, does not apply to bar the
 26 People’s public nuisance claim.

27 **29.** Legislative authorization does not bar the People’s public nuisance claim
 28 because, insofar as Walgreens’ conduct was a legal cause of the public nuisance proved

1 by the People, that conduct was not expressly authorized by the California State
2 Assembly.

3 29.1. California Civil Code § 3482 provides that “[n]othing which is done or
4 maintained under the express authority of a statute can be deemed a nuisance.” Section
5 3482 precludes an action for nuisance only “where the alleged wrongful acts are expressly
6 authorized by statute.” *Jones v. Union Pac. R.R. Co.*, 94 Cal. Rptr. 2d 661, 672 (Ct. App.
7 2000); *cf. Aron v. U-Haul Co. of Cal.*, 49 Cal. Rptr. 3d 555, 560 (Ct. App. 2006) (“Courts
8 ... may not create implied safe harbors.” (internal quotation marks omitted)).

9 29.2. Walgreens’ conduct is not expressly authorized by the CSA. To the
10 contrary, the CSA permits Walgreens to distribute and dispense controlled substances
11 only in accordance with the requirements of the statute. *See* 21 U.S.C. § 841 (making it
12 unlawful knowingly to distribute or dispense controlled substances “except as authorized
13 by this subchapter”). Distribution and dispensing that do not comport with the
14 requirements of the CSA are not expressly authorized and are, in fact, expressly
15 prohibited.

16 29.3. The California safe harbor provides no refuge for conduct that is unlawful
17 or otherwise fails to comply with law.

18 **30.** The statute of limitations does not bar the People’s public nuisance claim.

19 30.1. The statute of limitations does not apply to a public entity’s representative
20 public nuisance claim when the nuisance continues to exist. Cal. Civ. Code § 3490 (“No
21 lapse of time can legalize a public nuisance, amounting to an actual obstruction of public
22 right.”); *Mangini v. Aerojet-General Corp.*, 281 Cal. Rptr. 827, 838 (Ct. App. 1991)
23 (“Section 3490 has been construed to mean that the statute of limitations is no defense to
24 an action brought by a public entity to abate a public nuisance.”).

25 **V. Liability; Remedy; Judgment**

26 **31.** Walgreens is liable for the public nuisance of the opioid epidemic in San
27 Francisco.
28

1 **32.** The Court will enter judgment in the People’s favor after such further
2 proceedings to determine the appropriate remedy as the Court may order.
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1 DATED: July 20, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on July 20, 2022, service of this document on all Non-Stayed Defendants was accomplished by filing through the Court's ECF system.

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